AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Enbrel	Page:	1 of 13
Effective Date:	3/14/2025	Last Review Date:	2/13/2025
Applies to:	☒Illinois ☒Pennsylvania Kids	☒Florida Kids ☐Virginia	☒Maryland ☒Kentucky PRMD

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Enbrel under the patient's prescription drug benefit.

Description:

A. FDA-Approved Indications
   1. Moderately to severely active rheumatoid arthritis (RA)
   2. Moderately to severely active polyarticular juvenile idiopathic arthritis (pJIA) in patients aged 2 years and older
   3. Active psoriatic arthritis (PsA)
   4. Active ankylosing spondylitis (AS)
   5. Chronic moderate to severe plaque psoriasis (PsO) in patients aged 4 years or older who are candidates for systemic therapy or phototherapy
   6. Juvenile psoriatic arthritis in patients aged 2 years and older (JPsA)

B. Compendial Uses
   1. Non-radiographic axial spondylarthritis
   2. Oligoarticular juvenile idiopathic arthritis
   3. Reactive arthritis
   4. Hidradenitis suppurativa, severe, refractory
   5. Behçet's disease
   6. Graft versus host disease
   7. Immune checkpoint inhibitor toxicity

All other indications are considered experimental/investigational and not medically necessary.

Applicable Drug List:

Preferred Agent: Enbrel

Policy/Guideline:

Documentation:

A. **Rheumatoid arthritis (RA)**
   1. Initial requests:
      i. Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.
      ii. Laboratory results, chart notes, or medical record documentation of biomarker testing (i.e., rheumatoid factor [RF], anti-cyclic citrullinated peptide [anti-CCP],

and C-reactive protein [CRP] and/or erythrocyte sedimentation rate [ESR]) (if applicable).

2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response.

B. **Articular juvenile idiopathic arthritis (JIA)**
   1. Initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy.
   2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response.

C. **Psoriatic arthritis (PsA), ankylosing spondylitis (AS), non-radiographic axial spondyloarthritis (nr-axSpA), reactive arthritis, hidradenitis suppurativa, immune checkpoint inhibitor-related inflammatory arthritis, and chronic graft versus host disease**
   1. Initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.
   2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response.

D. **Plaque psoriasis (PsO)**
   1. Initial requests:
      i. Chart notes or medical record documentation of affected area(s) and body surface area (BSA) affected (if applicable).
      ii. Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.
   2. Continuation requests: Chart notes or medical record documentation of decreased body surface area (BSA) affected and/or improvement in signs and symptoms.

E. **Acute Graft versus host disease and immune checkpoint inhibitor-related toxicity (initial requests only):** Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

F. **Behçet's disease (initial requests only):** Chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy (if applicable).

Prescriber Specialty:
This medication must be prescribed by or in consultation with ONE of the following:

A. Rheumatoid arthritis, articular juvenile idiopathic arthritis, ankylosing spondylitis, non-radiographic axial spondylarthritis, reactive arthritis, and Behçet's disease: rheumatologist
B. Psoriatic arthritis and hidradenitis suppurativa: rheumatologist or dermatologist
C. Plaque psoriasis: dermatologist
D. Graft versus host disease: oncologist or hematologist
E. Immune checkpoint inhibitor-related inflammatory arthritis: oncologist, hematologist, or rheumatologist
F. Immune checkpoint inhibitor-related toxicity: oncologist, hematologist, or dermatologist

Criteria for Initial Approval:

A. Rheumatoid arthritis (RA)

1. Authorization of 12 months may be granted for adult members who have previously received a biologic or targeted synthetic drug (e.g., Rinvoq, Xeljanz) indicated for moderately to severely active rheumatoid arthritis.

2. Authorization of 12 months may be granted for adult members for treatment of moderately to severely active RA when ALL the following criteria are met:
   i. Member meets either of the following criteria:
      a. Member has been tested for either of the following biomarkers and the test was positive:
         1. Rheumatoid factor (RF)
         2. Anti-cyclic citrullinated peptide (anti-CCP)
      b. Member has been tested for ALL of the following biomarkers:
         1. RF
         2. Anti-CCP
         3. C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR)
   ii. Member meets EITHER of the following criteria:
      a. Member has experienced an inadequate response to at least a 3-month trial of methotrexate despite adequate dosing (i.e., titrated to at least 15 mg/week).
      b. Member has an intolerance or contraindication to methotrexate (see Appendix A).

B. Articular juvenile idiopathic arthritis (JIA)

1. Authorization of 12 months may be granted for members 2 years of age and older who have previously received a biologic or targeted synthetic drug (e.g., Xeljanz) indicated for moderately to severely active articular juvenile idiopathic arthritis.

2. Authorization of 12 months may be granted for members 2 years of age and older for the treatment of moderately to severely active articular juvenile idiopathic arthritis when any of the following criteria is met:

i. Member has had an inadequate response to methotrexate or another conventional synthetic drug (e.g., leflunomide, sulfasalazine, hydroxychloroquine) administered at an adequate dose and duration.
ii. Member has had an inadequate response to a trial of scheduled non-steroidal anti-inflammatory drugs (NSAIDs) and/or intra-articular glucocorticoids (e.g., triamcinolone hexacetonide) and one of the following risk factors for poor outcome:
    a. Involvement of ankle, wrist, hip, sacroiliac joint, and/or temporomandibular joint (TMJ)
    b. Presence of erosive disease or enthesitis
    c. Delay in diagnosis
    d. Elevated levels of inflammation markers
    e. Symmetric disease
iii. Member has risk factors for disease severity and potentially a more refractory disease course (see Appendix B) and member also meets one of the following:
    a. High-risk joints are involved (e.g., cervical spine, wrist, or hip).
    b. High disease activity.
    c. Is judged to be at high risk for disabling joint disease.

C. Psoriatic arthritis (PsA)

1. Authorization of 12 months may be granted for members 2 years of age or older who have previously received a biologic or targeted synthetic drug (e.g., Rinvoq, Otezla) indicated for active psoriatic arthritis.

2. Authorization of 12 months may be granted for members 2 years of age or older for treatment of active psoriatic arthritis when either of the following criteria is met:
    i. Member has mild to moderate disease and meets one of the following criteria:
        a. Member has had an inadequate response to methotrexate, leflunomide, or another conventional synthetic drug (e.g., sulfasalazine) administered at an adequate dose and duration.
        b. Member has an intolerance or contraindication to methotrexate or leflunomide (see Appendix A), or another conventional synthetic drug (e.g., sulfasalazine).
        c. Member has enthesitis or predominantly axial disease.
    ii. Member has severe disease.

D. Ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA)

1. Authorization of 12 months may be granted for adult members who have previously received a biologic or targeted synthetic drug (e.g., Rinvoq, Xeljanz) indicated for active ankylosing spondylitis or active non-radiographic axial spondyloarthritis.

2. Authorization of 12 months may be granted for adult members for treatment of active ankylosing spondylitis or active non-radiographic axial spondylarthritis when any of the following criteria is met:
   i. Member has experienced an inadequate response to at least two non-steroidal anti-inflammatory drugs (NSAIDs).
   ii. Member has an intolerance or contraindication to two or more NSAIDs.

E. Plaque psoriasis (PsO)

1. Authorization of 12 months may be granted for members 4 years of age or older who have previously a biologic or targeted synthetic drug (e.g., Sotyktu, Otezla) indicated for the treatment of moderate to severe plaque psoriasis.

2. Authorization of 12 months may be granted for treatment of moderate to severe plaque psoriasis in members 4 years of age or older when any of the following criteria is met:
   i. Crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
   ii. At least 10% of the body surface area (BSA) is affected.
   iii. At least 3% of body surface area (BSA) is affected and the member meets any of the following criteria:
      a. Member has had an inadequate response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine, or acitretin.
      b. Member has a clinical reason to avoid pharmacologic treatment with methotrexate, cyclosporine, and acitretin (see Appendix C).

F. Reactive arthritis

1. Authorization of 12 months may be granted for members who have previously received a biologic indicated for reactive arthritis.

2. Authorization of 12 months may be granted for treatment of reactive arthritis when either of the following criteria is met:
   i. Member has had an inadequate response to methotrexate or sulfasalazine.
   ii. Member has an intolerance or contraindication to methotrexate (see Appendix A) and sulfasalazine (e.g., porphyria, intestinal or urinary obstruction).

G. Hidradenitis suppurativa

1. Authorization of 12 months may be granted for members who have previously received a biologic indicated for the treatment of severe, refractory hidradenitis suppurativa.

2. Authorization of 12 months may be granted for treatment of severe, refractory hidradenitis suppurativa when either of the following is met:
   i. Member has had an inadequate response to an oral antibiotic used for the treatment of hidradenitis suppurativa (e.g., clindamycin, metronidazole, moxifloxacin, rifampin, tetracyclines) for at least 90 days.
   ii. Member has an intolerance or contraindication to oral antibiotics used for the treatment of hidradenitis suppurativa.

H. Graft versus host disease

Authorization of 12 months may be granted for treatment of graft versus host disease when EITHER of the following criteria is met:

1. Member has experienced an inadequate response to systemic corticosteroids.
2. Member has an intolerance or contraindication to corticosteroids.

I. Behçet's disease

1. Authorization of 12 months may be granted for members who have previously received Otezla, or a biologic indicated for the treatment of Behçet's disease.

2. Authorization of 12 months may be granted for the treatment of Behçet's disease when the member has had an inadequate response to at least one nonbiologic medication for Behçet's disease (e.g., apremilast, colchicine, systemic glucocorticoids, azathioprine).

J. Immune checkpoint inhibitor-related toxicity

1. Authorization of 1 month may be granted for treatment of immune checkpoint inhibitor-related toxicity when the member has Stevens-Johnson syndrome or toxic epidermal necrolysis.

2. Authorization of 12 months may be granted for treatment of immune checkpoint inhibitor-related toxicity when the member has moderate or severe immunotherapy-related inflammatory arthritis and EITHER of the following is met:
   i. Member has had an inadequate response to corticosteroids or a conventional synthetic drug (e.g., methotrexate, sulfasalazine, leflunomide, hydroxychloroquine).
   ii. Member has an intolerance or contraindication to corticosteroids and a conventional synthetic drug (e.g., methotrexate, sulfasalazine, leflunomide, hydroxychloroquine).

Continuation of Therapy:

A. Rheumatoid arthritis (RA)

Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for moderately to severely active rheumatoid arthritis and who achieve or maintain a positive clinical response as evidenced by disease activity improvement of at least 20% from baseline in tender joint count, swollen joint count, pain, or disability.

B. Articular juvenile idiopathic arthritis (JIA)

Authorization of 12 months may be granted for all members 2 years of age and older (including new members) who are using the requested medication for moderately to severely active articular juvenile idiopathic arthritis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in ANY of the following from baseline:

1. Number of joints with active arthritis (e.g., swelling, pain, limitation of motion)
2. Number of joints with limitation of movement
3. Functional ability

C. Psoriatic arthritis (PsA)

Authorization of 12 months may be granted for all members 2 years of age or older (including new members) who are using the requested medication for psoriatic arthritis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in ANY of the following from baseline:

1. Number of swollen joints
2. Number of tender joints
3. Dactylitis
4. Enthesitis
5. Axial disease
6. Skin and/or nail involvement
7. Functional status
8. C-reactive protein (CRP)

D. Ankylosing spondylitis (AS) and non-radiographic axial spondylarthritis (nr-axSpA)

Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for ankylosing spondylitis or non-radiographic axial spondylarthritis and who achieve or maintain a positive clinical response with the requested medication as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in ANY of the following from baseline:

1. Functional status
2. Total spinal pain
3. Inflammation (e.g., morning stiffness)

4. Swollen joints
5. Tender joints
6. C-reactive protein (CRP)

E. Plaque psoriasis (PsO)

Authorization of 12 months may be granted for all members 4 years of age or older (including new members) who are using the requested medication for moderate to severe plaque psoriasis and who achieve or maintain positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when ANY of the following is met:

1. Reduction in body surface area (BSA) affected from baseline
2. Improvement in signs and symptoms from baseline (e.g., itching, redness, flaking, scaling, burning, cracking, pain)

F. Reactive arthritis

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for reactive arthritis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition (e.g., tender joint count, swollen joint count, or pain).

G. Hidradenitis suppurativa

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for severe, refractory hidradenitis suppurativa and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when ANY of the following is met:

1. Reduction in abscess and inflammatory nodule count from baseline
2. Reduced formation of new sinus tracts and scarring
3. Decrease in frequency of inflammatory lesions from baseline
4. Reduction in pain from baseline
5. Reduction in suppuration from baseline
6. Improvement in frequency of relapses from baseline
7. Improvement in quality of life from baseline
8. Improvement on a disease severity assessment tool from baseline

H. Acute graft versus host disease and immune checkpoint inhibitor-related toxicity

All members (including new members) requesting authorization for continuation of therapy must meet all requirements in the coverage criteria

I. Chronic Graft versus host disease and immune checkpoint inhibitor toxicity

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for chronic graft versus host disease and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition.

J. Behçet's disease
Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for Behçet's disease and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition

K. Immune checkpoint inhibitor-related inflammatory arthritis
Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for immunotherapy-related inflammatory arthritis and who achieve or maintain a positive clinical response with the requested medication as evidenced by low disease activity or improvement in signs and symptoms of the condition.

Other Criteria:
For all indications: Member has had a documented negative tuberculosis (TB) test (which can include a tuberculosis skin test [TST] or an interferon-release assay [IGRA])* within 12 months of initiating therapy for persons who are naïve to biologic drugs or targeted synthetic drugs associated with an increased risk of TB.

* If the screening testing for TB is positive, there must be further testing to confirm there is no active disease (e.g., chest x-ray). Do not administer the requested medication to members with active TB infection. If there is latent disease, TB treatment must be started before initiation of the requested medication.

For all indications: Member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug for the same indication.

Appendix A: Examples of Contraindications to Methotrexate or Leflunomide
1. Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease
2. Breastfeeding
3. Blood dyscrasias (e.g., thrombocytopenia, leukopenia, significant anemia)
4. Elevated liver transaminases
5. History of intolerance or adverse event
6. Hypersensitivity
7. Interstitial pneumonitis or clinically significant pulmonary fibrosis
8. Myelodysplasia

9. Pregnancy or currently planning pregnancy
10. Renal impairment
11. Significant drug interaction

Appendix B: Risk factors for articular juvenile idiopathic arthritis

1. Positive rheumatoid factor
2. Positive anti-cyclic citrullinated peptide antibodies
3. Pre-existing joint damage

Appendix C: Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate, Cyclosporine, or Acitretin

1. Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease
2. Breastfeeding
3. Drug interaction
4. Cannot be used due to risk of treatment-related toxicity
5. Pregnancy or currently planning pregnancy
6. Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension)

Approval Duration and Quantity Restrictions:

Approval Duration:

Initial Approval: immune checkpoint inhibitor toxicity when the member has Stevens-Johnson syndrome or toxic epidermal necrolysis = 1 month; all others = 12 months

Renewal Approval: 12 months

Quantity Level Limit:

Medication	Standard Limit	Exception Limit*
Enbrel (etanercept) 25 mg per 0.5 mL prefilled syringe	8 syringes per 28 days	None
Enbrel (etanercept) 25 mg /0.5 mL single-dose vial	8 vials per 28 days	16 vials per 28 days
Enbrel (etanercept) 50 mg per 1 mL prefilled syringe/cartridge	4 syringes per 28 days	8 syringes per 28 days
Enbrel (etanercept) 50 mg per mL SureClick Autoinjector	4 cartridges per 28 days	8 cartridges per 28 days

*Exception limits apply to loading doses.

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