

UnitedHealthcare Pharmacy  
Clinical Pharmacy Programs

Program Number	2025 P 2197-12
Program	Prior Authorization/Medical Necessity
Medication	Enbrel® (etanercept)
P&T Approval Date	5/2020, 11/2020, 6/2021, 9/2021, 12/2021, 3/2022, 6/2022, 11/2022, 7/2023, 10/2024, 10/2025
Effective Date	1/17/2026

**1. Background:**

Enbrel (etanercept) is a tumor necrosis factor (TNF) blocker indicated for the treatment of rheumatoid arthritis (RA), polyarticular juvenile idiopathic arthritis (PJIA) in patients 2 years of age or older, psoriatic arthritis (PsA) in patients 2 years of age or older, ankylosing spondylitis (AS), and plaque psoriasis (PsO) in patients 4 years or older.

**2. Coverage Criteria<sup>a</sup>:**

**A. Rheumatoid Arthritis (RA)**

**1. Initial Authorization**

a. **Enbrel** will be approved based on **all** of the following criteria:

(1) Diagnosis of moderately to severely active rheumatoid arthritis

**-AND-**

(2) **One** of the following:

(a) History of failure to a 3 month trial of **one** non-biologic disease modifying anti-rheumatic drug (DMARD) [e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine] at maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)<sup>b</sup>

**-OR-**

(b) Patient has been previously treated with a systemic targeted immunomodulator FDA-approved for the treatment of rheumatoid arthritis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., adalimumab, Cimzia (certolizumab), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Simponi (golimumab), Xeljanz/Xeljanz XR (tofacitinib)].

**-OR-**

(c) **Both** of the following:

- i. Patient is currently on Enbrel therapy as documented by claims history or submission of medical records (Document date and duration of therapy):

-AND-

- ii. Patient has **not** received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the Amgen sponsored Enbrel Support program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Enbrel\*

-AND-

- (3) Patient is not receiving Enbrel in combination with another systemic targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Olumiant (baricitinib), Orenzia (abatacept), Rinvoq (upadacitinib), Simponi (golimumab), Xeljanz/Xeljanz XR (tofacitinib)] for treatment of the same indication.

-AND-

- (4) Prescribed by or in consultation with a rheumatologist

\* Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Amgen sponsored Enbrel Support program **shall be required** to meet initial authorization criteria as if patient were new to therapy.

**Authorization will be issued for 12 months.**

## 2. **Reauthorization**

- a. **Enbrel** will be approved based on **both** of the following criteria:

- (1) Documentation of positive clinical response to Enbrel therapy

-AND-

- (2) Patient is not receiving Enbrel in combination with another systemic targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Olumiant (baricitinib), Orenzia (abatacept), Rinvoq (upadacitinib), Simponi (golimumab), Xeljanz/Xeljanz XR (tofacitinib)] for treatment of the same indication.

**Authorization will be issued for 12 months.**

## **B. Polyarticular Juvenile Idiopathic Arthritis (PJIA)**

### 1. **Initial Authorization**

a. **Enbrel** will be approved based on **all** of the following criteria:

- (1) Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis

-AND-

- (2) Patient is not receiving Enbrel in combination with another systemic targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Simponi (golimumab), Xeljanz/Xeljanz XR (tofacitinib)] for treatment of the same indication.

-AND-

- (3) Prescribed by or in consultation with a rheumatologist

**Authorization will be issued for 12 months.**

## 2. **Reauthorization**

a. **Enbrel** will be approved based on **both** of the following criteria:

- (1) Documentation of positive clinical response to Enbrel therapy

-AND-

- (2) Patient is not receiving Enbrel in combination with another systemic targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Simponi (golimumab), Xeljanz/Xeljanz XR (tofacitinib)] for treatment of the same indication.

**Authorization will be issued for 12 months.**

## C. **Psoriatic Arthritis (PsA)**

### 1. **Initial Authorization**

a. **Enbrel** will be approved based on **all** of the following criteria:

- (1) Diagnosis of active psoriatic arthritis

-AND-

- (2) **One** of the following:

- (a) History of failure to a 3 month trial of methotrexate at maximally indicated dose, unless contraindicated or clinically significant adverse effects are experienced (document date and duration of trial)<sup>b</sup>

-OR-

- (b) Patient has been previously treated with a systemic targeted immunomodulator FDA-approved for the treatment of psoriatic arthritis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Orenzia (abatacept), Otezla (apremilast), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), Taltz (ixekizumab), Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), ustekinumab].

-OR-

- (c) **Both** of the following:

- i. Patient is currently on Enbrel therapy as documented by claims history or submission of medical records (Document date and duration of therapy):

-AND-

- ii. Patient has **not** received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the Amgen sponsored Enbrel Support program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Enbrel\*

-AND-

- (3) Patient is not receiving Enbrel in combination with another systemic targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Orenzia (abatacept), Otezla (apremilast), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), Taltz (ixekizumab), Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), ustekinumab] for treatment of the same indication.

-AND-

- (4) Prescribed by or in consultation with **one** of the following:

- (a) Rheumatologist  
(b) Dermatologist

\* Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Amgen sponsored Enbrel Support program **shall be required** to meet initial authorization criteria as if patient were new to therapy.

**Authorization will be issued for 12 months.**

## 2. Reauthorization

a. **Enbrel** will be approved based on **both** of the following criteria:

(1) Documentation of positive clinical response to Enbrel therapy

**-AND-**

(2) Patient is not receiving Enbrel in combination with another systemic targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Orencia (abatacept), Otezla (apremilast), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), Taltz (ixekizumab), Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), ustekinumab] for treatment of the same indication.

**Authorization will be issued for 12 months.**

## D. Plaque Psoriasis

### 1. Initial Authorization

a. **Enbrel** will be approved based on **all** of the following criteria:

(1) Diagnosis of chronic moderate to severe plaque psoriasis

**-AND-**

(2) **One** of the following:

(a) **All** of the following:

i. Greater than or equal to 3% body surface area involvement, palmoplantar, facial, genital involvement, or severe scalp psoriasis

**-AND-**

ii. History of failure to **one** of the following topical therapies, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial):

- a. Corticosteroids (e.g., betamethasone, clobetasol, desonide)
- b. Vitamin D analogs (e.g., calcitriol, calcipotriene)
- c. Tazarotene
- d. Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- e. Anthralin
- f. Coal tar

**-AND-**

iii. History of failure to of a 3 month trial of methotrexate at maximally indicated dose, unless contraindicated or clinically significant adverse effects are experienced (document date and duration of trial)<sup>b</sup>

**-OR-**

(b) Patient has been previously treated with a systemic targeted immunomodulator FDA-approved for the treatment of plaque psoriasis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Ilumya (tildrakizumab), Otezla (apremilast), Skyrizi (risankizumab), Siliq (brodalumab), Sotyktu (deucravacitinib), Taltz (ixekizumab), Tremfya (guselkumab), ustekinumab].

**-OR-**

(c) **Both** of the following:

i. Patient is currently on Enbrel therapy as documented by claims history or submission of medical records (Document date and duration of therapy):

**-AND-**

ii. Patient has **not** received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the Amgen sponsored Enbrel Support program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Enbrel\*

**-AND-**

(3) Patient is not receiving Enbrel in combination with another systemic targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Ilumya (tildrakizumab), Otezla (apremilast), Skyrizi (risankizumab), Siliq (brodalumab), Sotyktu (deucravacitinib), Taltz (ixekizumab), Tremfya (guselkumab), ustekinumab] for treatment of the same indication.

**-AND-**

(4) Prescribed by or in consultation with a dermatologist

\* Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Amgen sponsored Enbrel Support program **shall be required** to meet initial authorization criteria as if patient were new to therapy.

**Authorization will be issued for 12 months.**

## 2. Reauthorization

a. **Enbrel** will be approved based on **both** of the following criteria:

(1) Documentation of positive clinical response to Enbrel therapy

**-AND-**

(2) Patient is not receiving Enbrel in combination with another systemic targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Ilumya (tildrakizumab), Otezla (apremilast), Skyrizi (risankizumab), Siliq (brodalumab), Sotyktu (deucravacitinib), Taltz (ixekizumab), Tremfya (guselkumab), ustekinumab] for treatment of the same indication.

**Authorization will be issued for 12 months.**

## E. Ankylosing Spondylitis (AS)

### 1. Initial Authorization

a. **Enbrel** will be approved based on **all** of the following criteria:

(1) Diagnosis of active ankylosing spondylitis

**-AND-**

(2) **One** of the following:

(a) History of failure to **two** NSAIDs (e.g., ibuprofen, naproxen) at maximally indicated doses, each used for at least 4 weeks, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trials)

**-OR-**

(b) Patient has been previously treated with a systemic targeted immunomodulator FDA-approved for the treatment of ankylosing spondylitis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Olumiant (baricitinib), Orencia (abatacept), Simponi (golimumab), Rinvoq (upadacitinib), Taltz (ixekizumab), Xeljanz (tofacitinib)].

**-OR-**

(c) **Both** of the following:

- i. Patient is currently on Enbrel therapy as documented by claims history or submission of medical records (Document date and duration of therapy):

-AND-

- ii. Patient has **not** received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the Amgen sponsored Enbrel Support program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Enbrel\*

-AND-

- (3) Patient is not receiving Enbrel in combination with another systemic targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Olumiant (baricitinib), Orencia (abatacept), Simponi (golimumab), Rinvoq (upadacitinib), Taltz (ixekizumab), Xeljanz (tofacitinib)] for treatment of the same indication.

-AND-

- (4) Prescribed by or in consultation with a rheumatologist

\* Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Amgen sponsored Enbrel Support program **shall be required** to meet initial authorization criteria as if patient were new to therapy.

**Authorization will be issued for 12 months.**

## 2. **Reauthorization**

- a. **Enbrel** will be approved based on **both** of the following criteria:

- (1) Documentation of positive clinical response to Enbrel therapy

-AND-

- (2) Patient is not receiving Enbrel in combination with another systemic targeted immunomodulator [e.g., adalimumab, Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab), Cosentyx (secukinumab), Olumiant (baricitinib), Orencia (abatacept), Simponi (golimumab), Rinvoq (upadacitinib), Taltz (ixekizumab), Xeljanz (tofacitinib)] for treatment of the same indication.

**Authorization will be issued for 12 months.**

<sup>a</sup> State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

<sup>b</sup> For Connecticut, Kentucky and Mississippi business only a 30-day trial will be required.

### 3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

### 4. References:

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3. Yu, DT, van Tubergen A. Treatment of axial spondyloarthritis (ankylosing spondylitis and nonradiographic axial spondyloarthritis) in adults. Sieper, J (Ed). UpToDate. Waltham, MA: UpToDate Inc. <http://www.uptodate.com> (Accessed on October 10, 2019.)
4. Singh, JA, Guyatt, G, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. *Arthritis & Rheumatology*. 2019; 71(1): 5-32.
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6. Gottlieb A, Korman NJ, Gordon KB, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Psoriatic arthritis: Overview and guidelines of care for treatment with an emphasis on the biologics. *J Am Acad Dermatol* 2008;58(5):851-64.
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10. Nast A, et al; European S3-Guidelines on the systemic treatment of psoriasis vulgaris – update 2015 – short version – EFF in cooperation with EADV and IPC, *J Eur Acad Derm Venereol* 2015;29:2277-94.
11. Menter A, Korman NJ, Elmetts CA, Feldman SR, Gelfand JM, Gordon KB, Guidelines of care for the management of psoriasis and psoriatic arthritis: section 6. Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. *J Am Acad Dermatol*. 2011 Jul;65(1):137-74.

12. Gossec L, et al; European League Against Rheumatism (EULAR) recommendations for the management of psoriatic arthritis with pharmacological therapies: 2015 update, *Ann Rheum Dis* 2016;75:499-510.
13. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. *J Am Acad Dermatol.* 2019;80:1029-72.

Program	Prior Authorization/Medical Necessity - Enbrel (etanercept)
<b>Change Control</b>	
5/2020	New program
6/2020	Administrative change. Updated formatting numbers for psoriatic arthritis section with no change to clinical intent.
11/2020	Revised step therapy medications for psoriatic arthritis and psoriasis due to expanded indications. Removed continuation of therapy allowance.
6/2021	Removed prescriber requirement from reauthorization criteria. Added coverage criteria for patients previously treated with a biologic DMARD.
9/2021	Revised step requirements for rheumatoid arthritis, psoriatic arthritis, plaque psoriasis, and ankylosing spondylitis. Updated background and references.
12/2021	Updated the following with no change to clinical intent: updated conventional DMARD bypass language for rheumatoid arthritis, psoriatic arthritis and psoriasis, removed “biologic” from required preferred product criteria language, updated age requirement language and updated CT/KY footnote.
3/2022	Added Skyrizi as a preferred drug for active psoriatic arthritis.
6/2022	Added Rinvoq and Xeljanz as step therapy options for ankylosing spondylitis and psoriatic arthritis.
11/2022	Removed step requirement through preferred products and added continuation of therapy for RA, PsA, PsO, and AS.
7/2023	Updated not receiving in combination language to targeted immunomodulator and updated examples.
10/2024	Annual review with no change to coverage criteria. Updated background, state mandate footnote, and reference.
10/2025	Annual review. Updated combination examples and language with no change to clinical intent.