UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2021 P 2197-6
Program	Prior Authorization/Medical Necessity
Medication	Enbrel® (etanercept)
P&T Approval Date	5/2020, 11/2020, 6/2021, 9/2021, 12/2021
Effective Date	3/1/2022; Oxford only: 3/1/2022

1. Background:

Enbrel (etanercept) is indicated for reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active rheumatoid arthritis. It is also indicated for reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in patients 2 years of age or older. Enbrel is indicated for reducing signs and symptoms, inhibiting the progression of structural damage of active arthritis, and improving physical function in patients with psoriatic arthritis. It is indicated for reducing signs and symptoms in patients with active ankylosing spondylitis. Enbrel is also indicated for the treatment of patients (4 years or older) with chronic moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

2. Coverage Criteria[a]:

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) **Both** of the following:

i. **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

-OR-

b. Patient has been previously treated with a biologic or targeted synthetic DMARD 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., Cimzia (certolizumab), Humira (adalimumab), Simponi (golimumab),

Olumiant (baricitinib), Rinvoq (upadacitinib), Xeljanz/Xeljanz XR (tofacitinib)]

-AND-

ii. History of failure, contraindication, or intolerance to **two** of the following preferred products (Document drug, date, and duration of trial):

a. Cimzia (certolizumab)
b. Humira (adalimumab)
c. Simponi (golimumab)
d. Olumiant (baricitinib)
e. Rinvoq (upadacitinib)
f. Xeljanz/Xeljanz XR (tofacitinib)

-AND-

(3) Patient is not receiving Enbrel in combination with **either** of the following:

(a) Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept)]
(b) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)]

-AND-

(4) Prescribed by or in consultation with a rheumatologist

Authorization will be issued for 12 months.

2. Reauthorization

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

(1) Documentation of positive clinical response to Enbrel therapy

-AND-

(2) Patient is not receiving Enbrel in combination with **either** of the following:

(a) Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept)]
(b) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)]

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 **either** of the following:

(a) Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept)]
(b) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]

-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 **all** of the following criteria:

(1) Documentation of positive clinical response to Enbrel therapy

-AND-

(2) Patient is not receiving Enbrel in combination with **either** of the following:

(a) Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept)]
(b) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]

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) **Both** of the following:

i. **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)

-OR-

b. Patient has been previously treated with a biologic or targeted synthetic DMARD 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., Cimzia (certolizumab), Humira (adalimumab), Simponi (golimumab), Stelara (ustekinumab), Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), Otezla (apremilast)]

-AND-

ii. History of failure, contraindication, or intolerance to **two** of the following preferred products: (document drug, date, and duration of trial)

a. Humira (adalimumab)
b. Stelara (ustekinumab)
c. Cimzia (certolizumab)
d. Simponi (golimumab)
e. Tremfya (guselkumab)

-AND-

(3) Patient is not receiving Enbrel in combination with **any** of the following:

(a) Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept)]
(b) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
(c) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

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

(a) Rheumatologist
(b) Dermatologist

Authorization will be issued for 12 months.

2. Reauthorization

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

(1) Documentation of positive clinical response to Enbrel therapy

-AND-

(2) Patient is not receiving Enbrel in combination with **any** of the following:

(a) Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept)]
(b) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
(c) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

Authorization will be issued for 12 months.

D. Plaque Psoriasis

1. Initial Authorization

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

(1) Diagnosis of chronic moderate to severe plaque psoriasis

-AND-

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

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

i. **One** of the following:

a. **All** of the following:

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

-AND-

2. 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):

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

-AND-

3. 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)

-OR-

b. Patient has been previously treated with a biologic or targeted DMARD 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., Cimzia (certolizumab), Humira (adalimumab), Otezla (apremilast), Skyrizi (risankizumab-rzaa), Stelara (ustekinumab), Tremfya (guselkumab)].

-AND-

ii. History of failure, contraindication, or intolerance to **two** of the following preferred products: (document drug, date, and duration of trial)

a. Humira (adalimumab)
b. Stelara (ustekinumab)
c. Tremfya (guselkumab)
d. Cimzia (certolizumab)
e. Skyrizi (risankizumab)

-OR-

(b) Patient is less than 6 years of age

-OR-

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

i. Patient is 6 years to less than 18 years of age

-AND-

ii. History of failure, contraindication, or intolerance to Stelara (ustekinumab) (Document date and duration of trial)

-AND-

(3) Patient is not receiving Enbrel in combination with **any** of the following:

(a) Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept)]
(b) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
(c) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

(4) Prescribed by or in consultation with a dermatologist

Authorization will be issued for 12 months.

2. Reauthorization

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

(1) Documentation of positive clinical response to Enbrel therapy

-AND-

(2) Patient is not receiving Enbrel in combination with **any** of the following:

(a) Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept)]
(b) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
(c) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

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) **Both** of the following:

i. **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 biologic DMARD 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., Humira (adalimumab), Simponi (golimumab)].

-AND-

ii. History of failure, contraindication, or intolerance to **two** of the following preferred products:(document drug, date, and duration of trial)

a. Humira (adalimumab)
b. Cimzia (certolizumab)
c. Simponi (golimumab)

-AND-

(3) Patient is not receiving Enbrel in combination with **either** of the following:

(a) Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept)]
(b) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]

-AND-

(4) Prescribed by or in consultation with a rheumatologist

Authorization will be issued for 12 months.

2. Reauthorization

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

(1) Documentation of positive clinical response to Enbrel therapy

-AND-

(2) Patient is not receiving Enbrel in combination with **either** of the following:

(a) Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept)]
(b) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]

Authorization will be issued for 12 months.

[a] 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.
[b] For Connecticut business, only a 60-day trial will be required. For Kentucky 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:

1. Enbrel [package insert]. Thousand Oaks, CA: Immunex Corporation.; April 2021.
2. Ward MM, Deodhar, A, Gensler, LS, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. Arthritis & Rheumatology. 2019; 71(10): 1599-1613.
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.
5. Menter A, Gottlieb A, Feldman SR, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 1. Overview of psoriasis and guidelines of care for the treatment of psoriasis with biologics. J Am Acad Dermatol 2008; 58(5):826-50.
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.
7. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 3. Guidelines of care for the management and treatment of psoriasis with topical therapies. J Am Acad Dermatol 2009;60(4):643-59.
8. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Guidelines of care for the treatment of psoriasis with phototherapy and photochemotherapy. J Am Acad Dermatol 2010;62(1):114-35.
9. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Guidelines of care for the management and treatment of psoriasis with traditional systemic agents. J Am Acad Dermatol 2009;61(3):451-85.
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, Elmets 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)
Change Control	
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.