UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1029-13
Program	Prior Authorization/Notification
Medication	Enbrel® (etanercept)
P&T Approval Date	1/2007, 6/2008 , 4/2009, 6/2009, 12/2009, 7/2010, 11/2010, 7/2011, 11/2011, 7/2012, 11/2012, 2/2014, 2/2015, 3/2016, 3/2017, 3/2018, 3/2019, 3/2020, 3/2021, 3/2022, 3/2023, 7/2023, 10/2024
Effective Date	1/1/2025

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.[1]

2. Coverage Criteria[a]:

A. Rheumatoid Arthritis (RA)

1. **Initial Authorization**

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

      (1) Diagnosis of moderately to severely active rheumatoid arthritis

      -AND-

      (2) Patient is not receiving Enbrel in combination with another targeted immunomodulator [e.g., Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

      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 targeted immunomodulator [e.g., Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

Authorization will be issued for 12 months.

B. Polyarticular Juvenile Idiopathic Arthritis (PJIA)

1. **Initial Authorization**

   a. **Enbrel** will be approved based on **both** 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 targeted immunomodulator [e.g., Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

   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 targeted immunomodulator [e.g., Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

   Authorization will be issued for 12 months.

C. Psoriatic Arthritis (PsA)

1. **Initial Authorization**

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

      (1) Diagnosis of active psoriatic arthritis

      -AND-

      (2) Patient is not receiving Enbrel in combination with another targeted immunomodulator [e.g., Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Stelara (ustekinumab), Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz

(ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

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 targeted immunomodulator [e.g., Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Stelara (ustekinumab), Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), 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) Patient is not receiving Enbrel in combination with another targeted immunomodulator [e.g., Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Stelara (ustekinumab), Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Siliq (brodalumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

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 targeted immunomodulator [e.g., Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Stelara (ustekinumab), Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Siliq (brodalumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

Authorization will be issued for 12 months.

E. Ankylosing Spondylitis (AS)

1. **Initial Authorization**

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

(1) Diagnosis of active ankylosing spondylitis

-AND-

(2) Patient is not receiving Enbrel in combination with another targeted immunomodulator [e.g., Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

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 targeted immunomodulator [e.g., Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

Authorization will be issued for12 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.

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 and/or Step Therapy may be in place.

4. References:

1. Enbrel [package insert]. Thousand Oaks, CA: Immunex Corp.; October 2023.

Program	Prior Authorization/Notification – Enbrel (etanercept)
Change Control	
2/2014	Background updated. Concomitant therapy criterion condensed to list four biologic DMARDs and revised to include Xeljanz. Reauthorization criteria revised to standard verbiage and to include concomitant therapy criterion. Extended reauthorization duration to 24 months.
2/2015	Annual review with no change to coverage criteria. Minor reformatting. Updated clinical rules, background and references.
3/2016	Annual review. Added Otezla (apremilast) to the list of medications that the patient should not be receiving while on Enbrel therapy for plaque psoriasis and psoriatic arthritis. Added "polyarticular" to juvenile idiopathic arthritis. Updated reference.
3/2017	Annual review with no change to coverage criteria. Updated background and references.
3/2018	Annual review with no change to coverage criteria. Updated references.
3/2019	Annual review. Added Olumiant (baricitinib) to list of medications that patient should not be receiving while on Enbrel therapy for rheumatoid arthritis. Updated background.
3/2020	Annual review. Added Rinvoq (upadacitinib) to list of medications that patient should not be receiving while on Enbrel therapy for RA and Skyrizi (risankizumab) for PsO. Updated background.
3/2021	Annual review. Updated reauthorization approval length. Updated reference.
3/2022	Annual review. Updated references.
3/2023	Annual review. Changed Humira examples to adalimumab and added Rinvoq as a JAKI example. Added state mandate footnote. Updated background and reference.
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 and reference.