UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2018 P 1029-6
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
Effective Date	6/1/2018; Oxford only: 6/1/2018

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. <u>Rheumatoid Arthritis (RA)</u>

1. <u>Initial Authorization</u>

a. **Enbrel** will be approved based on **<u>both</u>** of the following criteria:

(1) Diagnosis of moderately to severely active rheumatoid arthritis

-AND-

(2) Patient is not receiving Enbrel in combination with **<u>either</u>** 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.

2. <u>Reauthorization</u>

a. **Enbrel** will be approved based on **<u>both</u>** 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 24 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 **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.

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 **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 24 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 **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.

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 **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 24 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 **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.

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 **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 24 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 **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.

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 **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 24 months.

3. **Additional Clinical Rules:**
   Supply limits and/or Step Therapy may be in place.

4. **References:**

   1. Enbrel [package insert]. Thousand Oaks, CA: Immunex Corp.; November 2017.

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.