

Clinical Pharmacy Program Guidelines for Enbrel

Program	Prior Authorization
Medication	Enbrel (etanercept)
Issue Date	9/2009
Pharmacy and Therapeutics Approval Date	3/2017
Effective Date	5/2017

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 of age and older with chronic moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

1. Coverage Criteria:

<p>A. <u>Rheumatoid Arthritis (RA)</u></p> <p>1. <u>Initial Authorization</u></p> <p>a. Diagnosis of moderately to severely active RA</p> <p style="text-align: center;">-AND-</p> <p>b. Prescribed or recommended by a rheumatologist</p> <p style="text-align: center;">-AND-</p> <p>c. History of failure, contraindication, or intolerance to one non-biologic disease modifying anti-rheumatic drug (DMARD) [eg, methotrexate, leflunomide, sulfasalazine]</p> <p style="text-align: center;">-AND-</p> <p>d. Patient is not receiving Enbrel in combination with any of the following:</p>

- (1) Biologic DMARD [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- (2) Janus kinase inhibitor [eg, Xeljanz (tofacitinib)]
- (3) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

Authorization will be issued for 12 months.

2. Reauthorization

- a. Documentation of positive clinical response to Enbrel therapy

-AND-

- b. Patient is not receiving Enbrel in combination with any of the following:

- (1) Biologic DMARD [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- (2) Janus kinase inhibitor [eg, Xeljanz (tofacitinib)]
- (3) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

Authorization will be issued for 12 months.

B. Juvenile Idiopathic Arthritis

1. Initial Authorization

- a. Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis

-AND-

- b. Prescribed or recommended by a rheumatologist

-AND-

- c. History of failure, contraindication, or intolerance to one of the following DMARDs:

- (1) Leflunomide (Arava)
- (2) Methotrexate (Rheumatrex/Trexall)

-AND-

d. Patient is not receiving Enbrel in combination with any of the following:

- (1) Biologic DMARD [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- (2) Janus kinase inhibitor [eg, Xeljanz (tofacitinib)]
- (3) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

Authorization will be issued for 12 months.

2. Reauthorization

a. Documentation of positive clinical response to Enbrel therapy

-AND-

b. Patient is not receiving Enbrel in combination with any of the following:

- (1) Biologic DMARD [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- (2) Janus kinase inhibitor [eg, Xeljanz (tofacitinib)]
- (3) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

Authorization will be issued for 12 months.

C. Psoriatic Arthritis

1. Initial Authorization

a. Diagnosis of active psoriatic arthritis

-AND-

b. Prescribed or recommended by a rheumatologist or dermatologist

-AND-

c. Patient is not receiving Enbrel in combination with any of the following:

- (1) Biologic DMARD [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- (2) Janus kinase inhibitor [eg, Xeljanz (tofacitinib)]
- (3) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

Authorization will be issued for 12 months.

2. Reauthorization

a. Documentation of positive clinical response to Enbrel therapy

-AND-

b. Patient is not receiving Enbrel in combination with any of the following:

- (1) Biologic DMARD [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- (2) Janus kinase inhibitor [eg, Xeljanz (tofacitinib)]
- (3) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

Authorization will be issued for 12 months.

D. Plaque Psoriasis

1. Initial Authorization

a. Diagnosis of moderate to severe chronic plaque psoriasis

-AND-

b. Prescribed or recommended by a dermatologist

-AND-

c. Patient is not receiving Enbrel in combination with any of the following:

- (1) Biologic DMARD [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- (2) Janus kinase inhibitor [eg, Xeljanz (tofacitinib)]
- (3) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

Authorization will be issued for 12 months.

2. Reauthorization

a. Documentation of positive clinical response to Enbrel therapy

-AND-

b. Patient is not receiving Enbrel in combination with any of the following:

- (1) Biologic DMARD [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- (2) Janus kinase inhibitor [eg, Xeljanz (tofacitinib)]
- (3) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

Authorization will be issued for 12 months.

E. Ankylosing Spondylitis

1. Initial Authorization

a. Diagnosis of ankylosing spondylitis

-AND-

b. Prescribed or recommended by a rheumatologist

-AND-

c. History of failure, contraindication, or intolerance to two or more NSAIDs

-AND-

d. Patient is not receiving Enbrel in combination with any of the following:

- (1) Biologic DMARD [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- (2) Janus kinase inhibitor [eg, Xeljanz (tofacitinib)]
- (3) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

Authorization will be issued for 12 months.

2. Reauthorization

a. Documentation of positive clinical response to Enbrel therapy

-AND-

b. Patient is not receiving Enbrel in combination with any of the following:

- (1) Biologic DMARD [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
- (2) Janus kinase inhibitor [eg, Xeljanz (tofacitinib)]
- (3) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

Authorization will be issued for 12 months.

2. References:

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Program	Program type – Prior Authorization
Change Control	
Date	Change
September 2009	Guidelines taken from previously approved AmeriChoice and Unison policies and updated based upon evidence in the literature.
December 2009	Guidelines revised to remove criteria for Ulcerative Colitis.
December 2010	Annual Review
December 2011	Annual Review <ul style="list-style-type: none"> • Changed requirement of history of failure of 2 DMARDs to history of failure of 1 DMARD for rheumatoid arthritis and psoriatic arthritis • Created Humira once weekly dosing criteria for rheumatoid arthritis • Specified “moderate to severe” for the severity of disease required for polyarticular JIA • Changed prerequisite medication requirements for polyarticular JIA and psoriatic arthritis • Specified severity of disease for plaque psoriasis • Changed prerequisite therapy to one phototherapy and one systemic therapy • Specified severity of disease for Crohn’s disease • Combined fistulizing and nonfistulizing Crohn’s disease to have the same prerequisite requirements.
June 2012	Cimzia added to policy for rheumatoid arthritis (III.A.) and Crohn’s disease (III.F.)
Sept 2012	Added option of additional alternative therapy failure of infliximab for initial therapy of Humira.

	No change to Cimzia for Crohn’s disease.
Feb 2015	<p>Converted existing multidrug policy to an Enbrel specific policy. Updated criteria to align with current UHC clinical criteria template.</p> <p>Removed age requirement for all indications.</p> <p>Removed prescriber requirement for all reauthorization criteria sections.</p> <p>JIA, initial therapy: Removed the requirement of trial of NDAIDs or corticosteroids, now only requires trial of methotrexate.</p> <p>Added “Janus kinase inhibitor” to all areas noting that the patient should not receive Cimzia in combination with other immunomodulator/biologic DMARDs.</p> <p>Added new requirement requiring trials of preferred alternatives to all sections: history of failure, contraindication, or intolerance to both* of the following: Cimzia and Humira (where indicated for the specific diagnosis) or Continuation of prior Enbrel therapy.</p> <p>*Both Cimzia and Humira are required only when both drugs indicated for the diagnosis. If only one preferred drugs is indicated for a specific diagnosis, then only a trial of the one drug is required (eg, Humira for JIA).</p>
March 2016	<p>Removed prerequisite therapy requirements throughout policy that required other biologic DMARD trials before Enbrel.</p> <p>Updated Juvenile Idiopathic Arthritis (JIA) initial therapy to include leflunomide as a part of the DMARD requirement</p> <p>Annual Review- Updated policy template</p>
October 2016	Updated background with expanded age for plaque psoriasis
March 2017	<p>Added Otezla to list of medications not to be used with Enbrel.</p> <p>Updated policy template.</p>