UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Enbrel

Program	Prior Authorization
Medication	Enbrel (etanercept)
Markets in scope	Arizona, CA, Colorado, Hawaii, Maryland, Nevada, New Jersey, New York, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	9/2009
Pharmacy and Therapeutics Approval Date	11/2020
Effective Date	12/2020

1. Background

Enbrel is a tumor necrosis factor (TNF) blocker indicated for the treatment of rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, and plaque psoriasis.

2. Coverage Criteria:

A. Rheumatoid Arthritis (RA)

1. Initial Authorization

a. Diagnosis of moderately to severely active RA

-AND-

b. 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 within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)

-AND-

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

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

-AND-

d. Prescribed by or in consultation with a rheumatologist

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

-AND-

c. Prescribed by or in consultation with a rheumatologist

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

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

-AND-

c. Prescribed by or in consultation with a rheumatologist

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

-AND-

c. Prescribed by or in consultation with a rheumatologist

Authorization will be issued for 12 months.

C. Psoriatic Arthritis

1. Initial Authorization

a. Diagnosis of active psoriatic arthritis

-AND-

b. History of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)

-AND-

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

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

-AND-

d. Prescribed by or in consultation with **one** of the following:

(1) Rheumatologist
(2) Dermatologist

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

-AND-

c. Prescribed by or in consultation with **one** of the following:

(1) Rheumatologist
(2) Dermatologist

Authorization will be issued for 12 months.

D. Plaque Psoriasis

1. Initial Authorization

a. Diagnosis of moderate to severe chronic plaque psoriasis

-AND-

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

-AND-

c. **Both** of the following:

(1) 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-

(2) History of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)

-AND-

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

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

-AND-

e. Prescribed by or in consultation with a dermatologist

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

-AND-

c. Prescribed by or in consultation with a dermatologist

Authorization will be issued for 12 months.

E. Ankylosing Spondylitis

1. Initial Authorization

a. Diagnosis of active ankylosing spondylitis

-AND-

b. History of failure to two NSAIDs (e.g., ibuprofen, naproxen) at maximally indicated doses, each used for at least 4 weeks within the last 3 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trials)

-AND-

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

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

-AND-

d. Prescribed by or in consultation with a rheumatologist

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

-AND-

c. Prescribed by or in consultation with a rheumatologist

Authorization will be issued for 12 months.

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: Amgen Inc.; August 2020.
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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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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.
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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, 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.

Program	Program type – Prior Authorization
Change Control	
Date	Change
9/2009	Guidelines taken from previously approved AmeriChoice and Unison policies and updated based upon evidence in the literature.
12/2009	Guidelines revised to remove criteria for Ulcerative Colitis.
12/2010	Annual Review
12/2011	Annual Review • 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.
6/2012	Cimzia added to policy for rheumatoid arthritis (III.A.) and Crohn’s disease (III.F.)

9/2012	Added option of additional alternative therapy failure of infliximab for initial therapy of Humira. No change to Cimzia for Crohn's disease.
2/2015	Converted existing multidrug policy to an Enbrel specific policy. Updated criteria to align with current UHC clinical criteria template. Removed age requirement for all indications. Removed prescriber requirement for all reauthorization criteria sections. JIA, initial therapy: Removed the requirement of trial of NDAIDs or corticosteroids, now only requires trial of methotrexate. Added "Janus kinase inhibitor" to all areas noting that the patient should not receive Cimzia in combination with other immunomodulator/biologic DMARDs. 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. *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).
3/2016	Removed prerequisite therapy requirements throughourt policy that required other biologic DMARD trials before Enbrel. Updated Juvenile Idiopathic Arthritis (JIA) initial therapy to include leflunomide as a part of the DMARD requirement Annual Review- Updated policy template
10/2016	Updated background with expanded age for plaque psoriasis
3/2017	Added Otezla to list of medications not to be used with Enbrel. Updated policy template.
4/2017	Added hydroxychloroquine to example list of non-biologic DMARDs
8/2018	Annual review. Updated references.

3/2019	Removed prescriber check and prerequisite medications to align with other programs. Updated background and references.
11/2019	Revised prerequisite therapies for psoriasis, psoriatic arthritis, and ankylosing spondylitis. Added body surface requirement for use in psoriasis. Updated references.
12/2019	Revised additional prerequisite therapies and added documentation of drug, date, and duration of trials.
5/2020	Added prescriber requirement. Minor revisions to prerequisite therapy requirements. Changed BSA requirement to 3% to align with current psoriasis guidelines.
11/2020	Updated reference.