UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Humira

Program	Prior Authorization
Medication	Humira (adalimumab)
Markets in scope	Arizona, California, Hawaii, Maryland, Nevada, New Jersey, New York, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	9/2009
Pharmacy and Therapeutics Approval Date	5/2020
Effective Date	7/2020

1. Background:

Humira (adalimumab) is indicated in adults with moderately to severely active rheumatoid arthritis (RA), active psoriatic arthritis (PsA), active ankylosing spondylitis (AS), moderately to severely active Crohn's disease (CD), moderately to severely active ulcerative colitis (UC), and moderate to severe plaque psoriasis. Humira is also indicated for moderately to severely active polyarticular juvenile idiopathic arthritis (JIA) in patients 2 years of age and older, moderately to severely active CD in patients 6 years of age and older, moderate to severe hidradenitis suppurativa in patients 12 years of age and older, and non-infectious intermediate, posterior, and panuveitis in adults and pediatric patients 2 years of age and older.

2. Coverage Criteria:

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

1. <u>Initial Authorization</u>

a. Diagnosis of moderately to severely active rheumatoid arthritis

-AND-

b. History of failure to a 3 month trial of **<u>one</u>** 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 Humira in combination with **<u>any</u>** 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 Humira therapy

-AND-

b. Patient is not receiving Humira 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. Polyarticular Juvenile Idiopathic Arthritis

1. Initial Authorization

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

-AND-

b. Patient is not receiving Humira 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 Humira therapy

-AND-

b. Patient is not receiving Humira 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 Humira 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 Humira therapy

-AND-

b. Patient is not receiving Humira 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 Humira 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 Humira therapy

-AND-

b. Patient is not receiving Humira 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 Humira 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 Humira therapy

-AND-

b. Patient is not receiving Humira 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.

F. Adult Crohn's Disease

1. Initial Authorization

a. Diagnosis of moderately to severely active Crohn's disease

-AND-

b. **One** of the following:

(1) History of failure to one of the following conventional therapies at maximally indicated doses within the last 3 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial):

(a) Corticosteroids (e.g., prednisone, methylprednisolone, budesonide)
(b) Azathioprine (Imuran)
(c) 6-mercaptopurine (Purinethol)
(d) Methotrexate (Rheumatrex, Trexall)

-OR-

(2) Patient has lost response or intolerant to infliximab (e.g., Remicade, Inflectra, Renflexis)

-AND-

c. Patient is not receiving Humira 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 gastroenterologist

Authorization will be issued for 12 months.

2. Reauthorization

a. Documentation of positive clinical response to Humira therapy

-AND-

b. Patient is not receiving Humira 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 gastroenterologist

Authorization will be issued for 12 months.

G. Pediatric Crohn's Disease

1. Initial Authorization

a. Diagnosis of moderately to severely active Crohn's disease

-AND-

b. History of failure to one of the following conventional therapies at maximally indicated doses within the last 3 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial):

(1) Corticosteroids (e.g., prednisone, methylprednisolone, budesonide)
(2) Azathioprine (Imuran)
(3) 6-mercaptopurine (Purinethol)
(4) Methotrexate (Rheumatrex, Trexall)

-AND-

c. Patient is not receiving Humira 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 gastroenterologist

Authorization will be issued for 12 months.

2. Reauthorization

a. Documentation of positive clinical response to Humira therapy

-AND-

b. Patient is not receiving Humira 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 gastroenterologist

Authorization will be issued for 12 months.

H. Ulcerative Colitis

1. Initial Authorization

a. Diagnosis of moderately to severely active ulcerative colitis

-AND-

b. History of failure to **one** of the following conventional therapies at maximally indicated doses within the last 3 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial):

(1) Corticosteroids (e.g., prednisone, methylprednisolone, budesonide)
(2) 6-mercaptopurine (Purinethol)
(3) Azathioprine (Imuran)
(4) Aminosalicylates (e.g., mesalamine, sulfasalazine)

-AND-

c. Patient is not receiving Humira 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 gastroenterologist

Authorization will be issued for 12 months.

2. Reauthorization

a. Documentation of positive clinical response to Humira therapy

-AND-

b. Patient is not receiving Humira 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 gastroenterologist

Authorization will be issued for 12 months.

I. Hidradenitis Suppurativa

1. Initial Authorization

a. Diagnosis of moderate to severe hidradenitis suppurativa (i.e., Hurley Stage II or III)

-AND-

b. History of failure to at least one oral antibiotic (e.g., doxycycline, clindamycin, rifampin) at maximally indicated doses within the last 3 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)

-AND-

c. Patient is not receiving Humira 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 dermatologist

Authorization will be issued for 12 months.

2. Reauthorization

a. Documentation of positive clinical response to Humira therapy

-AND-

b. Patient is not receiving Humira 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.

J. Uveitis (UV)

1. Initial Authorization

a. Diagnosis of non-infectious uveitis

-AND-

b. Uveitis is classified as **one** of the following:

(1) intermediate
(2) posterior
(3) panuveitis

-AND-

c. History of failure to at least one corticosteroid (e.g., prednisolone, prednisone) at maximally indicated dose within the last 3 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)

-AND-

d. History of failure to at least one systemic non-biologic immunosuppressant (e.g., methotrexate, cyclosporine, azathioprine, mycophenolate) at maximally indicated dose within the last 3 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)

-AND-

e. Patient is not receiving Humira 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-

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

(1) Rheumatologist
(2) Ophthalmologist

Authorization will be issued for 12 months.

2. Reauthorization

a. Documentation of positive clinical response to Humira therapy

-AND-

b. Patient is not receiving Humira 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) Ophthalmologist

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:

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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. Ingram, JR. Hidradenitis suppurativa: Treatment. Dellavalle, RP, Dahl, MV (Ed). UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com (Accessed on October 29, 2019.)
14. Rosenbaum, JT. Uveitis: Treatment. Trobe, J (Ed). UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com (Accessed on October 30, 2019).

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 a Humira 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. Added “Janus kinase inhibitor” to all areas noting that the patient should not receive Cimzia in combination with other immunomodulator/biologic DMARDs.
12/2015	Policy updated with the new FDA-approved indication for hidradenitis suppurativa Prescriber requirement was modified to read, “Prescribed by or in consultation with a(n)….” for all indications Removed endnotes related to age restrictions since criteria no longer have age restrictions.
3/2016	Updated Juvenile Idiopathic Arthritis (JIA) initial therapy to include leflunomide as a part of the DMARD requirement Updated the list of conventional therapies required in the Crohn’s disease (CD) criteria to remove aminosalicylates Updated the list of conventional therapies required for ulcerative colitis (UC) criteria to add aminosalicylates Removed all “notes to prescriber” Annual Review- Updated policy template
10/2016	Added not to use in combination with Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)] to all sections Added prescriber requirement for Hidradenitis Suppurativa Added criteria for Uveitis
3/2017	Updated ulcerative colitis initial authorization duration to 12 months to match initial authorization durations for other indications. Updated policy template.
4/2017	Added hydroxychloroquine to example list of non-biologic DMARDs
8/2018	Minor updates to the background and formatting. Updated references.
3/2019	Removed prescriber check. Revised UC reauthorization criteria to align with language in other programs. Removed prerequisite medications from JIA and AS sections. Updated references.
11/2019	Revised prerequisite therapies for psoriasis, psoriatic arthritis, and

	ankylosing spondylitis. Added body surface requirement for use in psoriasis. Updated background and references.
12/2019	Revised additional prerequisite therapies and added documentation of drug, date, and duration of trials. Updated background and references.
4/2020	Added a section for pediatric Crohn's Disease to align with label.
5/2020	Added prescriber requirement. Minor revisions to prerequisite therapy requirements. Changed BSA requirement to 3% to align with current psoriasis guidelines.