UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Cimzia

Program	Prior Authorization
Medication	Cimzia (certolizumab pegol)
Markets in scope	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:

Cimzia (certolizumab) is a tumor necrosis factor (TNF) blocker indicated for reducing signs and symptoms of Crohn's disease and maintaining clinical response in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy. Cimzia is also indicated for the treatment of adults with moderately to severely active rheumatoid arthritis, active psoriatic arthritis, active ankylosing spondylitis, moderate to severe plaque psoriasis in patients who are candidates for systemic therapy or phototherapy, and active non-radiographic axial spondyloarthritis with objective signs of inflammation.

2. Coverage Criteria:

A. <u>Crohn's disease</u>

1. <u>Initial Authorization</u>

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):

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

-AND-

c. Patient is not receiving Cimzia 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 Cimzia therapy

-AND-

b. Patient is not receiving Cimzia 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.

B. 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 Cimzia 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 Cimzia therapy

-AND-

b. Patient is not receiving Cimzia 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 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 Cimzia 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 Cimzia therapy

-AND-

b. Patient is not receiving Cimzia 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. Ankylosing Spondylitis or Non-Radiographic Axial Spondyloarthritis

1. Initial Authorization

a. Diagnosis of active ankylosing spondylitis or non-radiographic axial spondyloarthritis

-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 Cimzia 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 Cimzia therapy

-AND-

b. Patient is not receiving Cimzia 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.

E. Plaque Psoriasis

1. Initial Authorization

a. Diagnosis of moderate to severe 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 Cimzia 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. <u>Reauthorization</u>

a. Documentation of positive clinical response to Cimzia therapy

-AND-

b. Patient is not receiving Cimzia 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-

c. Prescribed by or in consultation with a dermatologist

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. Cimzia [package insert]. Smyrna, GA: UCB. April 2019.
2. Ward MM, Deodhar, A, Gensler, LS, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. Arthritis & Rheumatology. 2019; 71(10): 1599-1613.
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.
5. Menter A, Gottlieb A, Feldman SR, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 1. Overview of psoriasis and guidelines of care for the treatment of psoriasis with biologics. J Am Acad Dermatol 2008; 58(5):826-50.
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.
7. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 3. Guidelines of care for the management and treatment of psoriasis with topical therapies. J Am Acad Dermatol 2009;60(4):643-59.
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.
9. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Guidelines of care for the management and treatment of psoriasis with traditional systemic agents. J Am Acad Dermatol 2009;61(3):451-85.
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 a Cimzia 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.
3/2016	Updated criteria for psoriatic arthritis (PsA) to remove the requirement for history of one oral DMARD to be consistent with other biologic DMARD criteria Updated the list of conventional therapies required in the Crohn's disease (CD) criteria to remove aminosalicylates Removed all "notes to prescriber" Added formulary note in preface

	Annual Review- Updated policy template
10/2016	Annual Review – no change to criteria
3/2017	Added Otezla to list of medications not to be taken with Cimzia. Updated references and policy template.
4/2017	Added hydroxychloroquine to example list of non-biologic DMARDs
8/2018	Updated background and review criteria for plaque psoriasis indication. Updated references.
3/2019	Removed prescriber check. Modified prerequisite language for Crohn's disease. Updated references.
5/2019	Added non-radiographic axial spondyloarthritis to the program. Updated background and reference.
11/2019	Revised Crohn's disease conventional therapy requirement to match other programs. 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.
5/2020	Added prescriber requirement. Minor revisions to prerequisite therapy requirements. Changed BSA requirement to 3% to align with current psoriasis guidelines.