UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Cimzia

Program	Prior Authorization
Medication	Cimzia (certolizumab pegol)
Issue Date	9/2009
Pharmacy and Therapeutics Approval Date	3/2017
Effective Date	5/2017

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. Examples of conventional therapy include anti-inflammatory drugs, corticosteroids, and oral immunosuppressive agents. Cimzia is also indicated for the treatment of adults with moderately to severely active rheumatoid arthritis. Cimzia is indicated for the treatment of adult patients with active psoriatic arthritis. It is also indicated for the treatment of adults with active ankylosing spondylitis.

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, contraindication, or intolerance to one or more of the following conventional therapies:

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

-AND-

c. Prescribed or recommended by a gastroenterologist

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-AND-

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

(1) Biologic DMARD [eg, 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)]

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 [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. Rheumatoid Arthritis (RA)

1. Initial Authorization

a. Diagnosis of moderately to severely active RA

-AND-

b. Prescribed or recommended by a rheumatologist

-AND-

c. History of failure, contraindication, or intolerance to one non-biologic disease modifying anti-rheumatic drug (DMARD) [eg, methotrexate, leflunomide, sulfasalazine]

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-AND-

d. Patient is not receiving Cimzia 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 Cimzia therapy

-AND-

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

(1) Biologic DMARD [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]

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(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 Cimzia therapy

-AND-

b. Patient is not receiving Cimzia 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. 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 Cimzia 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)]

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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 [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.

3. 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 • Changed requirement of history of failure of 2 DMARDs to history of failure of 1 DMARD for rheumatoid arthritis and

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	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	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.
March 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

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	Annual Review- Updated policy template
October 2016	Annual Review – no change to criteria
March 2017	Added Otezla to list of medications not to be taken with Cimzia. Updated references and policy template.

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