

Clinical Pharmacy Program Guidelines for Cimzia- ARIZONA

Program	Prior Authorization
Medication	Cimzia (certolizumab pegol)

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:

<p>A. <u>Crohn's disease</u></p> <p>1. <u>Initial Authorization</u></p> <p>a. Diagnosis of moderately to severely active Crohn's disease</p> <p align="center">-AND-</p> <p>b. History of failure, contraindication, or intolerance to one or more of the following conventional therapies:</p> <p>(1) Corticosteroids (eg, prednisone, methylprednisolone, budesonide) (2) 6-mercaptopurine (Purinethol) (3) Azathioprine (Imuran) (4) Methotrexate (Rheumatrex, Trexall)</p> <p align="center">-AND-</p> <p>c. Prescribed or recommended by a gastroenterologist</p> <p align="center">-AND-</p> <p>d. Patient is not receiving Cimzia in combination with any of the following:</p> <p>(1) Biologic DMARD [eg, Enbrel (etanercept), Humira (adalimumab),</p>

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

-AND-

e. One of the following:

- (1) History of failure, contraindication, or intolerance to Humira (adalimumab)

-OR-

- (2) For continuation of prior Cimzia therapy

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, hydroxychloroquine]

-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)]

-AND-

- e. One of the following:

- (1) History of failure, contraindication, or intolerance to both of the following:
 - (a) Humira (adalimumab)
 - (b) Enbrel (etanercept)

-OR-

- (2) For continuation of prior Cimzia therapy

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)]
- (2) Janus kinase inhibitor [eg, Xeljanz (tofacitinib)]
- (3) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

d. One of the following:

- (1) History of failure, contraindication, or intolerance to both of the following:
 - (a) Humira (adalimumab)
 - (b) Enbrel (etanercept)

-OR-

- (2) For continuation of prior Cimzia therapy

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)]

-AND-

- e. One of the following:

- (1) History of failure, contraindication, or intolerance to both of the following:
 - (a) Humira (adalimumab)
 - (b) Enbrel (etanercept)

-OR-

- (2) For continuation of prior Cimzia therapy

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:**

1. Cimzia Prescribing Information, UCB. January 2017.
2. Schreiber S, Rutgeerts P, Fedorak RN, et al. A randomized, placebo-controlled trial of certolizumab pegol (CDP870) for treatment of Crohn's disease. *Gastroenterology*. 2005; 129(3): 807-18.
3. Sandborn WJ, Feagan BG, Stoinov S, et al. Certolizumab pegol for the treatment of Crohn's disease. *N Engl J Med*. 2007 Jul 19; 357(3):228-38.
4. Schreiber WJ, Khaliq-Kareemi M, Lawrance IC, et al. Maintenance therapy with certolizumab pegol for Crohn's disease. *N Engl J Med*. 2007 Jul 19; 357(3):239-50
5. Lichtenstein GR, Abreu MT, Cohen R, Tremaine W. American Gastroenterological Association Institute medical position statement on corticosteroids, immunomodulators, and infliximab in inflammatory bowel disease. *Gastroenterology* 2006 Mar;130(3):935-9.
6. American College of Rheumatology 2008 Recommendations for the use of nonbiologic and biologic disease-modifying antirheumatic drugs in rheumatoid arthritis. *Arthritis Rheum*.2008;59(6):762-784.
7. Furst DE, Keystone EC, Braun J, et al. Updated consensus statement on biological agents for the treatment of rheumatic diseases. *Ann Rheum Dis*. 2011;70(Suppl 1):i2-i36.
8. Keystone E, van der Heijde D, Mason Jr. D, et al. Certolizumab pegol plus methotrexate is significantly more effective than placebo plus methotrexate in active rheumatoid arthritis. *Arthritis Rheum*. 2008; 58(11): 3319-3329.
9. Fleischmann R, Vencovsky J, van Vollenhoven RF, et al. Efficacy and safety of certolizumab pegol monotherapy every 4 weeks in patients with rheumatoid arthritis

- failing previous disease-modifying antirheumatic therapy: the FAST4WARD study. *Ann Rheum Dis.* 2009; 68: 805-811.
10. Smolen J, Landewe RB, Mease P, et al. Efficacy and safety of certolizumab pegol plus methotrexate in active rheumatoid arthritis: the RAPID 2 study: A randomized controlled trial. *Ann Rheum Dis.* 2009; 68: 797-804.
 11. Felson DT, Anderson JJ, Boers M, et al. American College of Rheumatology preliminary definition of improvement in rheumatoid arthritis. *Arthritis Rheum.* 1995;38:727-735.
 12. Felson DT, Anderson JJ, Boers M, et al. American College of Rheumatology preliminary core set of disease activity measures for rheumatoid arthritis clinical trials. *Arthritis Rheum.* 1993; 36 (6): 729-740.
 13. Per clinical consult with rheumatologist, June 30, 2011.
 14. Lichtenstein GR, Hanauer SB, Sandborn WJ, and The Practice Parameters Committee of the American College of Gastroenterology. Management of Crohn's disease in adults. *Am J Gastroenterol.* 2009;104:465-483.
 15. Singh JA, Furst DE, Bharat A, et al. 2012 update of the 2008 American College of Rheumatology recommendations for the use of disease-modifying antirheumatic drugs and biologic agents in the treatment of rheumatoid arthritis. *Arthritis Care Res.* 2012;64(5):625-39.
 16. Braun J, van den Berg R, Baraliakos X, et al. 2010 update of the ASAS/EULAR recommendations for the management of Ankylosing spondylitis. *Ann Rheum Dis.* 2011;70:896-904.
 17. van der Heijde, Sieper J, Maksymowych WP, et al. 2010 update of the international ASAS recommendations for the use of anti-TNF agents in patients with axial spondyloarthritis. *Ann Rheum Dis.* 2011;70:905-908.
 18. Kyle S, Chandler D, Griffiths EM, et al. Guideline for anti-TNF-? therapy in psoriatic arthritis. *Rheumatology.* 2005;44:390-397.
 19. Furst DE, Keystone EC, Braun J, et al. Updated consensus statement on biological agents for the treatment of rheumatic diseases, 2011. *Ann Rheum Dis.* 2012;71(Supp II):i2-i45.

Program	Program type – Prior Authorization
Change Control	
Date	Change
August 2017	New policy specific to Arizona.