UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2021 P 1017-11
Program	Prior Authorization/Notification
Medication	Cimzia® (certolizumab)
P&T Approval Date	1/2007, 6/2008, 4/2009, 6/2009, 12/2009, 7/2010, 11/2010, 7/2011, 11/2011, 7/2012, 11/2012, 11/2013, 2/2015, 3/2016, 3/2017, 3/2018, 9/2018, 5/2019, 9/2019, 9/2020, 9/2021
Effective Date	12/1/2021; Oxford only: N/A

1. Background:

Cimzia (certolizumab) is a tumor necrosis factor (TNF) blocker indicated for reducing signs and symptoms of Crohn's disease (CD) 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 (RA), treatment of adult patients with active psoriatic arthritis (PsA), treatment of adults with active ankylosing spondylitis (SpA), treatment of adults with moderate to severe plaque psoriasis (PS) who are candidates for systemic therapy or phototherapy, and for the treatment of adults with non-radiographic axial spondyloarthritis (nr-axSpA), with objective signs of inflammation.

2. Coverage Criteria:

A. Crohn's Disease (CD)

1. Initial Authorization

a. **Cimzia** will be approved based on **all** of the following criteria:

(1) Diagnosis of moderately to severely active Crohn's disease

-AND-

(2) Patient has had an inadequate response to conventional therapies (examples include anti-inflammatory drugs, corticosteroids, or oral immunosuppressive agents)

-AND-

(3) Patient is not receiving Cimzia in combination with **either** of the following:

(a) Biologic DMARD [e.g., Actemra (tocilizumab), Enbrel (etanercept), Rituxan (rituximab), Orencia (abatacept)]

(b) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]

Authorization will be issued for 12 months.

2. <u>Reauthorization</u>

a. **Cimzia** will be approved based on **<u>both</u>** of the following criteria:

(1) Documentation of positive clinical response to Cimzia therapy

-AND-

(2) Patient is not receiving Cimzia in combination with **<u>either</u>** of the following:

(a) Biologic DMARD [e.g., Actemra (tocilizumab), Enbrel (etanercept), Rituxan (rituximab), Orencia (abatacept)][1]
(b) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]

Authorization will be issued for 12 months.

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

1. <u>Initial Authorization</u>

a. **Cimzia** will be approved based on **<u>both</u>** of the following criteria:

(1) Diagnosis of moderately to severely active rheumatoid arthritis

-AND-

(2) Patient is not receiving Cimzia in combination with **<u>either</u>** of the following:

(a) Biologic DMARD [e.g., Actemra (tocilizumab), Enbrel (etanercept), Rituxan (rituximab), Orencia (abatacept)][1]
(b) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]

Authorization will be issued for 12 months.

2. <u>Reauthorization</u>

a. **Cimzia** will be approved based on **<u>both</u>** of the following criteria:

(1) Documentation of positive clinical response to Cimzia therapy

-AND-

(2) Patient is not receiving Cimzia in combination with **either** of the following:

(a) Biologic DMARD [e.g., Actemra (tocilizumab), Enbrel (etanercept), Rituxan (rituximab), Orencia (abatacept)][1]
(b) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]

Authorization will be issued for 12 months.

C. Psoriatic Arthritis (PsA)

1. Initial Authorization

a. **Cimzia** will be approved based on **both** of the following criteria:

(1) Diagnosis of active psoriatic arthritis

-AND-

(2) Patient is not receiving Cimzia in combination with **any** of the following:

(a) Biologic DMARD [e.g., Actemra (tocilizumab), Enbrel (etanercept), Rituxan (rituximab), Orencia (abatacept)][1]
(b) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
(c) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

Authorization will be issued for 12 months.

2. Reauthorization

a. **Cimzia** will be approved based on **both** of the following criteria:

(1) Documentation of positive clinical response to Cimzia therapy

-AND-

(2) Patient is not receiving Cimzia in combination with **any** of the following:

(a) Biologic DMARD [e.g., Actemra (tocilizumab), Enbrel (etanercept), Rituxan (rituximab), Orencia (abatacept)][1]
(b) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
(c) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

Authorization will be issued for 12 months.

D. Ankylosing Spondylitis (AS) and Non-radiographic Axial Spondyloarthritis (nr-axSpA)

1. Initial Authorization

a. **Cimzia** will be approved based on **both** of the following criteria:

(1) Diagnosis of active ankylosing spondylitis or non-radiographic axial spondyloarthritis

-AND-

(2) Patient is not receiving Cimzia in combination with **either** of the following:

(a) Biologic DMARD [e.g., Actemra (tocilizumab), Enbrel (etanercept), Rituxan (rituximab), Orencia (abatacept)][1]
(b) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]

Authorization will be issued for 12 months.

2. Reauthorization

a. **Cimzia** will be approved based on **both** of the following criteria:

(1) Documentation of positive clinical response to Cimzia therapy

-AND-

(2) Patient is not receiving Cimzia in combination with **either** of the following:

(a) Biologic DMARD [e.g., Actemra (tocilizumab), Enbrel (etanercept), Rituxan (rituximab), Orencia (abatacept)][1]
(b) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]

Authorization will be issued for 12 months.

E. Plaque Psoriasis (PS)

1. Initial Authorization

a. **Cimzia** will be approved based on **both** of the following criteria:

(1) Diagnosis of moderate to severe plaque psoriasis

-AND-

(2) Patient is not receiving Cimzia in combination with any of the following:

(a) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cosentyx (secukinumab), Simponi (golimumab)]
(b) Janus kinase inhibitor [eg, Xeljanz (tofacitinib)]
(c) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

Authorization will be issued for 12 months.

2. <u>Reauthorization</u>

a. **Cimzia** will be approved based on **<u>both</u>** of the following criteria:

(1) Documentation of positive clinical response to Cimzia therapy

-AND-

(2) Patient is not receiving Cimzia in combination with **<u>any</u>** of the following:

(a) Biologic DMARD [eg, Enbrel (etanercept), Humira (adalimumab), Cosentyx (secukinumab), Simponi (golimumab)][1]
(b) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
(c) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

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, Inc; September 2019.

Program	Prior Authorization/Notification - Cimzia (certolizumab)
Change Control	
11/2013	Background updated. New criteria for psoriatic arthritis and ankylosing spondylitis. Concomitant therapy criterion condensed to list four biologic DMARDs and revised to include Xeljanz. Reauthorization criteria revised to standard verbiage and to include concomitant therapy criterion. Extended reauthorization duration to 24 months.
9/2014	Administrative change - Tried/Failed exemption for State of New Jersey removed.
2/2015	Annual review with no change to coverage criteria. Minor reformatting. Updated background and references.
3/2016	Annual review. Added Otezla (apremilast) to the combination criteria for Psoriatic Arthritis. Updated references.
3/2017	Annual review with no change to coverage criteria. Updated references.
3/2018	Annual review with no change to coverage criteria.
9/2018	Added coverage for plaque psoriasis. Updated background and references.
5/2019	Addition of non-radiographic axial spondyloarthritis diagnosis. Updated background and reference.
9/2019	Annual review. Updated reference.
9/2020	Annual review. Changed reauthorization durations to 12 months. Updated reference.
9/2021	Annual review with no change to coverage criteria.