CareSource

PHARMACY POLICY STATEMENT **Ohio Medicaid**	
DRUG NAME	Cimzia (certolizumab pegol)
BILLING CODE	For medical – J0717 (1 unit = 1 mg) Must use valid NDC code for self-administered product
BENEFIT TYPE	Pharmacy or Medical
SITE OF SERVICE ALLOWED	Outpatient/Office/Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Preferred Product) QUANTITY LIMIT— 1200 per 28 days
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Cimzia (certolizumab pegol) is a **preferred** product and will only be considered for coverage under the **pharmacy or medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

ANKYLOSING SPONDYLITIS (AS)

For **initial** authorization:

1. Member must be 18 years of age or older; AND
2. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), an interferon-release assay (IGRA)) within 12 months prior to starting therapy; AND
3. Medication must be prescribed by a rheumatologist; AND
4. Member has had back pain for 3 months or more that began before the age of 50; AND
5. Member shows at least **one** of the following signs or symptoms of Spondyloarthritis:
   a) Arthritis;
   b) Elevated serum C-reactive protein;
   c) Inflammation at the tendon, ligament or joint capsule insertions;
   d) Positive HLA-B27 test;
   e) Limited chest expansion;
   f) Morning stiffness or post rest stiffness for 1 hour or more;
   g) Increased occiput to wall distance; AND
6. Member meets at least **one** of the following scenarios:
   a) Member has Axial (spinal) disease;
   b) Member has peripheral arthritis without axial involvement and has tried and failed treatment with methotrexate or sulfasalazine. Treatment failure requires at least 3 months of therapy without an adequate response; AND
7. Member has tried and failed to respond to treatment with at least **two** prescription NSAIDs taken at the maximum recommended dosages. Treatment failure requires at least 4 weeks of therapy with each NSAID without an adequate response.
8. **Dosage allowed:** Inject 400 mg subcutaneously once a week at weeks 0, 2, and 4 and then 200 mg every other week or 400 mg every four weeks.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:
1. Must have been retested for TB with a negative result within the past 12 months; AND
2. Member must be in compliance with all other initial criteria; AND
3. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CROHN'S DISEASE (CD)

For **initial** authorization:
1. Member is 18 years of age or older with moderate to severe active CD; AND
2. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), an interferon-release assay (IGRA)) within 12 months prior to starting therapy; AND
3. Medication must be prescribed by a gastroenterologist; AND
4. Member has had a documented trial (for at least 12 weeks) and inadequate response to 6-mercaptopurine, azathioprine, methotrexate or corticosteroids; OR
5. Member has severe disease, as indicated by at least **one** of the following:
   a) Esophageal or gastroduodenal disease;
   b) Extensive small-bowel disease involving more than 100 cm;
   c) History of colonic resection;
   d) History of two or more small-bowel resections;
   e) Perianal or rectal disease.
6. **Dosage allowed:** Inject 400 mg subcutaneously once a week at weeks 0, 2, and 4 and then 400 mg every four weeks.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:
1. Must have been retested for TB with a negative result within the past 12 months; AND
2. Member must be in compliance with all other initial criteria; AND
3. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

PLAQUE PSORIASIS (PsO)

For **initial** authorization:
1. Member must be 18 years of age or older; AND
2. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), an interferon-release assay (IGRA)) within 12 months prior to starting therapy; AND
3. Medication must be prescribed by a rheumatologist or dermatologist; AND
4. Member has PsO for 6 months or longer; AND
5. Member has PsO involves 10% or more of the body surface area (BSA); AND
6. Member's Psoriasis Area and Severity Index (PASI) score is greater than or equal to 12; AND
7. Member has tried and failed to respond to treatment with at least **one** of the following:
   a) At least 12 weeks of photochemotherapy (i.e., psoralen plus ultraviolet A therapy);
   b) At least 12 weeks of phototherapy (i.e., UVB light therapy, Excimer laser treatments; tanning beds emit mostly UVA light and therefore would not meet this criteria);
   c) At least a 4 week trial with topical antipsoriatic agents (i.e., anthralin, calcipotriene, coal tar, corticosteroids, tazarotene); AND

8. Member has tried and failed to respond to treatment with traditional first-line oral/systemic therapies (i.e., cyclosporine, methotrexate, acitretin) for at least 12 weeks.
9. **Dosage allowed:** 400 mg (given as 2 subcutaneous injections of 200 mg each) every other week. For some members (with body weight ≤ 90 kg), a dose of 400 mg (given as 2 subcutaneous injections of 200 mg each) initially and at Weeks 2 and 4, followed by 200 mg every other week may be considered.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:
1. Member must be retested for TB with a negative result within the past 12 months; AND
2. Member must be in compliance with all other initial criteria; AND
3. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease (e.g., documented member's PASI score improvement, etc.).

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

PSORIATIC ARTHRITIS (PsA)

For **initial** authorization:
1. Member must be 18 years of age or older; AND
2. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), an interferon-release assay (IGRA)) within 12 months prior to starting therapy; AND
3. Medication must be prescribed by a rheumatologist or dermatologist; AND
4. Member meets at least **one** of the following scenarios:
   a) Member has predominantly axial disease (i.e., sacroiliitis or spondylitis) as indicated by radiographic evidence;
   b) Member has shown symptoms of predominantly axial disease (i.e., sacroiliitis or spondylitis) for more than 3 months (i.e., limited spinal range of motion, spinal morning stiffness for more than 30 minutes) AND has tried and failed to respond to treatment with at least 2 prescription NSAIDs taken at the maximum recommended dosages. Treatment failure requires at least 4 weeks of therapy with each NSAID without an adequate response;
   c) Member has predominately non-axial disease (e.g., peripheral synovitis or dactylitis or nail involvement) and has tried and failed to respond to treatment with at least 8-week trial of methotrexate and NSAID taken at the maximum recommended dosages (if unable to tolerate or has contraindication to methotrexate than 8-week trial of sulfasalazine or azathioprine or cyclosporine).
5. **Dosage allowed:** Inject 400 mg subcutaneously once a week at weeks 0, 2, and 4 and then 200 mg every other week or 400 mg every four weeks.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:
1. Must have been retested for TB with a negative result within the past 12 months; AND
2. Member must be in compliance with all other initial criteria; AND
3. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

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RHEUMATOID ARTHRITIS (RA)

For **initial** authorization:

1. Member must be 18 years of age or older with moderate to severe active RA; AND
2. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), an interferon-release assay (IGRA)) within 12 months prior to starting therapy; AND
3. Medication must be prescribed by a rheumatologist; AND
4. Member must have tried and failed treatment with at least **two** non-biologic DMARDS (i.e., methotrexate, hydroxychloroquine, sulfasalazine, azathioprine, cyclosporine and leflunomide) or must have documented contraindication to all non-biologic DMARDS. Treatment trial duration with each non-biologic DMARD agent must have been at least 12 weeks.
5. **Dosage allowed:** Inject 400 mg subcutaneously once a week at weeks 0, 2, and 4 and then 200 mg every other week thereafter.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:

1. Must have been retested for TB with a negative result within the past 12 months; AND
2. Member must be in compliance with all other initial criteria; AND
3. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Cimzia (certolizumab pegol) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Active infections
- Asthma
- Cellulitis
- Dissecting scalp cellulitis
- For use in combination with other TNF-inhibitors (i.e., Humira, Kineret, Enbrel, Remicade)
- Giant-cell arteritis
- Guttate psoriasis
- Infectious uveitis
- Lupus perino
- Osteoarthritis
- Recurrent pregnancy loss
- Relapsing polychondritis
- Sarcoidosis
- Sciatica
- Spondyloarthritis (other than ankylosing spondylitis)
- Takayasu's arteritis
- Vogt-Koyanagi

DATE	ACTION/DESCRIPTION
05/08/2017	New policy for Cimzia created. Policies SRx-0041 and SRx-0042 achieved. New diagnosis of AS with criteria was added. For diagnosis of CD: TNF inhibitor Humira and corticosteroids trials were added. For PsA: TNF inhibitors Humira and Enbrel were listed as required trials. For RA: non-biologic DMARDS were listed, and TNF inhibitors Humira and Enbrel were listed as required trials. List of diagnoses considered not medically necessary was added.
08/15/2018	Exception to pregnant member or those who are planning on becoming pregnant or are currently breastfeeding was added to each diagnosis in TNF requirement criterion. New indication of Plaque Psoriasis added. A requirement to have documented radiographic change involving the sacroiliac joints for diagnosis of AS was removed, and criteria of increased occiput to wall distance and post rest stiffness were added. Drug trials length were clarified as 4 weeks in length with each NSAID and 12 weeks in length with each Enbrel and Humira.
02/26/2019	Status changed to preferred. Humira and Enbrel trials removed from criteria; references edited. Initial authorization length increased to 12 months for PsO. TB test allowed to be done within 12 months prior to initiation of therapy; chest x-ray option removed. Symptoms of back pain for AS extended till before age of 50. Other drugs options allowed for PsA if there is an intolerance or contraindication to methotrexate. “Immunosuppressant therapies” changed to “treatment of traditional first-line oral/systemic” therapies. Reauthorization criteria on documented member’s PASI score improvement incorporated into general chart noted documentation requirements.

References:

1. Cimzia [prescribing information]. Smyrna, GA: UCB, Inc.; May 2018.
2. 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 May;58(5):826-50.
3. Gottlieb A, Korman NJ, Gordon KB, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 2. Psoriatic arthritis: overview and guidelines of care for treatment with an emphasis on the biologics. J Am Acad Dermatol. 2008 May;58(5):851-64.
4. Menter A, Korman NJ, Elmets CA, Feldman SR, Gelfand JM, Gordon KB,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 Apr;60(4):643-59.
5. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: section 4. Guidelines of care for the management and treatment of psoriasis with traditional systemic agents. J Am Acad Dermatol. 2009 Sep;61(3):451-85.
6. Menter A, Korman NJ, Elmets CA, Feldman SR, Gelfand JM, Gordon KB, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 5. Guidelines of care for the treatment of psoriasis with phototherapy and photochemotherapy. J Am Acad Dermatol. 2010 Jan;62(1):114-35.
7. 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.
8. Singh, J., et.al.,(2012). 2012 Update of the 2008 American College of Rheumatology Recommendations for the Use of Disease-Modifying Anti-rheumatic Drugs and Biologic Agents in the Treatment of Rheumatoid Arthritis. Arthritis Care & Research, 64(5), 625-639. doi:10.1002/acr.21641.
9. Beukelman T, Patkar NM, Saag KG, et al. 2011 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis: initiation and safety monitoring of therapeutic agents for the treatment of arthritis and systemic features. Arthritis Care Res. (Hoboken). 2011 Apr;63(4):465-82.
10. Saag KG, Teng GG, Patkar NM, et al. American College of Rheumatology 2008 Recommendations for the Use of Non- biologic and Biologic Disease-Modifying Anti-rheumatic Drugs in Rheumatoid Arthritis. Arthritis Care & Research. Arthritis Rheum 2008;59(6):762-84.
11. Lichtenstein GR, Hanauer SB, Sandborn WJ, Practice Parameters Committee of American College of Gastroenterology. Management of Crohn's disease in adults. American Journal of Gastroenterology 2009;104(2):465-83; quiz 464, 484. DOI: 10.1038/ajg.2008.168. (Reaffirmed 2014 Oct)

12. Sandborn, W., Binion, D., Persley, K., Atreja, A., & Kosinski, L. (2014). AGA Institute Guidelines for the Identification, Assessment and Initial Medical Treatment in Crohn's Disease: Clinical Decision Support Tool. AGA Institute. Retrieved August 14, 2015, from www.gastro.org/IBDcarepathway.
13. Krause ML, Amin S, Makol A. Use of DMARDs and biologics during pregnancy and lactation in rheumatoid arthritis: what the rheumatologist needs to know. Therapeutic Advances in Musculoskeletal Disease. 2014;6(5):169-184. doi:10.1177/1759720X14551568.
14. Clowse ME, Wolf DC, Förger F, et al. Pregnancy Outcomes in Subjects Exposed to Certolizumab Pegol. The Journal of Rheumatology. 2015;42(12):2270-2278. doi: 10.3899/jrheum.140189.
15. Clowse ME, Förger F, Hwang C, et al. Minimal to no transfer of certolizumab pegol into breast milk: results from CRADLE, a prospective, postmarketing, multicentre, pharmacokinetic study. Annals of the Rheumatic Diseases 2017;76:1890-1896.
16. Hsu S, Papp KA, Lebwohl MG, et al. Consensus guidelines for the management of plaque psoriasis. Arch Dermatol. 2012 Jan;148(1):95-102.
17. ClinicalTrials.gov. Identifier: NCT02326298. An Efficacy and Safety Study of Two Dose Levels of Certolizumab Pegol (CZP) in Subjects With Plaque Psoriasis (PSO) (CIMPASI-1). Available at: https://clinicaltrials.gov/ct2/show/NCT02326298?term=NCT02326298&rank=1.
18. ClinicalTrials.gov. Identifier: NCT02326272. A Study to Evaluate the Efficacy and Safety of Two Dose Levels of Certolizumab Pegol (CZP) in Subjects With Plaque Psoriasis (PSO) (CIMPASI-2). Available at: https://clinicaltrials.gov/ct2/show/NCT02326272?term=NCT02326272&rank=1.
19. ClinicalTrials.gov. Identifier: NCT02346240. Efficacy and Safety Study of Certolizumab Pegol (CZP) Versus Active Comparator and Placebo in Subjects With Plaque Psoriasis (PSO) (CIMPACT). Available at: https://clinicaltrials.gov/ct2/show/NCT02346240?term=NCT02346240&rank=1.
20. Harrold LR, et al. One-year risk of serious infection in patients treated with certolizumab pegol as compared with other TNF inhibitors in a real-world setting: data from a national U.S. rheumatoid arthritis registry. Arthritis Res Ther. 2018 Jan 2;20(1):2.
21. Bykerk VP, et al Update on the safety profile of certolizumab pegol in rheumatoid arthritis: an integrated analysis from clinical trials. Ann Rheum Dis. 2015 Jan;74(1):96-103.
22. Bello S, et al. FRI0190 Safety of certolizumab pegol in rheumatoid arthritis patients with previous hepatitis b virus exposure. Ann Rheum Dis. 2013;72:A436.
23. Mariette X, et al. The incidence of tuberculosis in patients treated with certolizumab pegol across indications: impact of baseline skin test results, more stringent screening criteria and geographic region. RMD Open. 2015 Apr 28;1(1):e000044.

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