

Pharmacy Management Drug Policy

SUBJECT: Cimzia® (Certolizumab pegol) - for Ankylosing Spondylitis, Crohn's Disease, Psoriatic Arthritis and Rheumatoid Arthritis

POLICY NUMBER: PHARMACY-07

EFFECTIVE DATE: 5/2009

LAST REVIEW DATE: 1/1/2020

If the member's subscriber contract excludes coverage for a specific service or prescription drug, it is not covered under that contract. In such cases, medical or drug policy criteria are not applied. Medical or drug policies apply to commercial and Health Care Reform products only when a contract benefit for the specific service exists.

DESCRIPTION:

Cimzia® (Certolizumab pegol) is a pegylated humanized antibody Fab. fragment of tumor necrosis factor alpha (TNF-alpha) monoclonal antibody. Certolizumab pegol binds to and selectively neutralizes human TNF-alpha activity. TNF α is a key proinflammatory cytokine with a central role in inflammatory processes. Since it is not a complete antibody (lacks Fc region), it does not induce complement activation, antibody-dependent cell-mediated cytotoxicity, or apoptosis. Pegylation of certolizumab allows for delayed elimination and therefore an extended half-life.

Cimzia® is indicated for:

- reducing the 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
- the treatment of adults with moderately to severely active rheumatoid arthritis (RA)
- the treatment of adult patients with active psoriatic arthritis (PsA)
- the treatment of adult patients with active ankylosing spondylitis (AS)
- the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy

POLICY:

Based upon our assessment and review of the peer-reviewed literature Cimzia® has been medically proven to be effective and therefore, **medically necessary** for the treatment of the following diagnoses if specific criteria are met:

A. Ankylosing Spondylitis

1. A diagnosis of ankylosing spondylitis established by a rheumatologist
2. Must be actively followed by and the drug prescribed by a rheumatologist
3. Presence of refractory disease defined by failure of at least **TWO** different NSAIDs given at maximum dosage for at least 1 month each
4. If self-administered, there must also be documentation of drug failure or serious side effects with **TWO** of the following preferred products: Enbrel, Humira, Cosentyx
5. If office administered, there must also be documentation of drug failure or serious side effects with Inflectra
6. Approved dosing is as follows:
 - a. Initial dose of 400mg (given as 2 subcutaneous injections of 200mg) at week 0, 2 and 4. A quantity limit override to allow 6 injections for the first month will be granted.
 - b. Maintenance dose of 200mg every other week or 400mg every 4 weeks with approved quantity limit of 2 injections/28 days

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B. Non-Radiographic Axial Spondylitis (nr-axSpA)

1. A diagnosis of non-radiographic axial spondylitis established by a rheumatologist
2. Must be actively followed by and the drug prescribed by a rheumatologist
3. Presence of refractory disease defined by failure of at least TWO different NSAIDs given as maximum dosage for at least 1 month each

C. Crohn's Disease

1. Patient has a diagnosis of moderately to severely active Crohn's disease **AND**
2. Moderate to severe disease - Crohn's Disease Activity Index (CDAI) score of 220-450. Typically described as having more prominent symptoms of fever, significant weight loss, abdominal pain or tenderness, intermittent nausea or vomiting or significant anemia.
3. Must be actively followed by and the drug prescribed by a Gastroenterologist
4. Patient meets at least **ONE** of the following criteria:
 - a. Patient continues to experience disease flare despite complete and adequate therapy with a corticosteroid (such as prednisone or budesonide). Typically response is noted within 14 days of initiating therapy **OR**
 - b. Patient is steroid-dependent (unable to taper off of steroids) despite treatment with azathioprine, 6-mercaptopurine or methotrexate **OR**
 - c. Documentation is provided that azathioprine, 6-mercaptopurine, or methotrexate is ineffective, contraindicated or not tolerated **AND**
5. If self-administered and under 18 years of age, there must also be documentation of drug failure or serious side effects to Humira
6. If self-administered and 18 years of age or older, there must also be documentation of serious side effects or drug failure to Humira **AND** Stelara.
7. If office administered, there must also be documentation of serious side effects or drug failure to TWO of the following the preferred products: Inflectra and Entyvio
8. Authorization period and dosing limitations:
 - a. Initial dose 400mg (given as 2 subcutaneous injections of 200mg) at week 0, 2 and 4. A quantity limit override to allow 6 injections for the first month will be granted.
 - b. In patients who obtain a clinical response, the recommended maintenance regimen is 400mg every 4 weeks

D. Psoriatic Arthritis

1. A diagnosis of definitive psoriatic arthritis established by a Rheumatologist or Dermatologist **AND**
2. Member must have some clinical features of psoriatic arthritis such as: involvement of the DIP joints, an asymmetric distribution of joint disease, spondyloarthritis, sausage digits, new bone formation on radiographs, cutaneous findings, and the characteristic nail manifestations of psoriatic arthritis (nail pitting, onycholysis & other lesions, which include leukonychia, red spots in the lunula, and nail plate crumbling) all may be present.
3. Member must be actively followed by and the drug prescribed by a Rheumatologist or Dermatologist **AND**
4. If self-administered, there must also be documentation of drug failure or serious side effects to **TWO** of the preferred products: : Enbrel, Humira, Stelara, Xeljanz/XR, Cosentyx

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5. If office administered, there must also be documentation of drug failure or serious side effects to Inflectra
6. Cimzia dosing will be authorized as:
 - a. Initial dose of 400mg (given as 2 subcutaneous injections of 200mg) at week 0, 2 and 4. A quantity limit override to allow 6 injections for the first month will be granted.
 - b. Maintenance dose of 200mg every other week (or 400mg every 4 weeks) with approved quantity limit of 2 injections/28 days

E. Rheumatoid Arthritis

1. Member must be actively followed by and the drug prescribed by a Rheumatologist **AND**
2. Member must have active moderate to severe rheumatoid arthritis **AND**
3. Member must have failed to respond to and/or is intolerant to approved disease-modifying antirheumatic drug (DMARD) agents, such as methotrexate, azathioprine, sulfasalazine, or hydroxychloroquine, either alone or in combination for a 3 month period **AND**
4. If self-administered, there must also be documentation of drug failure or serious side effects to **TWO** of the following preferred products: Actemra SC, Enbrel, Humira, Xeljanz/Xeljanz XR, Rinvoq
5. If office administered, there must also be documentation of drug failure or serious side effects to Inflectra, **plus** a 2nd immunomodulator or biologic medication (Actemra SC, Enbrel, Humira, Xeljanz/Xeljanz XR).
6. Approved dosing is as follows:
 - a. Initial dose of 400mg (given as 2 subcutaneous injections of 200mg) at week 0, 2 and 4. A quantity limit override to allow 6 injections for the first month will be granted.
 - b. Maintenance dose of 200mg every other week or 400mg every 4 weeks with approved quantity limit of 2 injections/28 days.
7. Low disease activity or remission should be considered treatment targets for members receiving certolizumab. Members with moderate or high disease activity >3 months due to lack of or loss of benefit should discontinue certolizumab and switch to another biologic agent.
8. Members with high disease activity who fail certolizumab therapy due to a serious adverse effect should switch to a non-TNF biologic. Member with moderate or high disease activity who fails certolizumab therapy due to non-serious adverse effects should switch to another TNF-blocker or a non-TNF biologic agent.

F. Plaque Psoriasis

1. Member must be followed by a dermatologist or rheumatologist **AND**
2. Must have moderate to severe chronic plaque psoriasis that involves at least 10% body surface area. Consideration will be given to those who have severe disease of the hands or feet or other areas causing disruption in normal activities, but have less than 10% body surface area involvement **AND**
3. Member must be a candidate for systemic therapy (i.e., acitretin, methotrexate, or cyclosporine therapy) **AND** had a trial period of at least 3 months or had developed serious side effects or have a contraindication to the above mentioned agents
 - a. If systemic therapy is contraindicated, then of the following must be attempted for a reasonable period of time (at least 3 months):

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- i. UVB in combination with a topical therapy such as coal tar, steroids or tazarotene **OR**
 - ii. PUVA in combination with topical corticosteroids **OR**
 - iii. Medium/High potency topical steroids in combination with anthralin, calcipotriene, or tazarotene **AND**
4. Member must also have a documented drug failure or serious side effects to **TWO** of the following agents: Humira, Otezla, Stelara, Skyrizi, Tremfya
5. Approved dosing: 400 mg (given as 2 subcutaneous injections of 200 mg each) every other week. For some patients (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..

APPROVAL TIME PERIODS:

Line of Business	Rx Initial approval	Rx Recertification	Medical Initial approval	Medical Recertification
Medicaid Managed Care (MMC)/Child Health Plus (CHP)	2 years	2 years	6 months	12 months
Commercial/Exchange	2 years	2 years	Outpatient hospital: 6 months	Outpatient hospital: 6 months
			Home Care/Office Based: 2 years	Home Care/Office Based: 2 years
Medicare	Already defined in policy	Already defined in policy	Outpatient hospital: 6 months	Outpatient hospital: 6 months
			Home Care/Office Based: 2 years	Home Care/Office Based: 2 years

POLICY GUIDELINES:

1. Prior-authorization is contract dependent.
2. Continued approval at time of recertification will require documentation that the drug is providing ongoing benefit to the patient in terms of improvement or stability in disease state or condition. Such documentation may include progress notes, imaging or laboratory findings, and other objective or subjective measures of benefit which support that continued use of the requested product is medically necessary. Also, ongoing use of the requested product must continue to reflect the current policy's preferred formulary. Recertification reviews may result in the requirement to try more cost-effective treatment alternatives as they become available (i.e.; generics, biosimilars, or other guideline-supported treatment options). Requested dosing must continue to be consistent with FDA-approved or off-label/guideline-supported dosing recommendations.
3. For contracts where Insurance Law § 4903(c-1), and Public Health Law § 4903(3-a) are applicable, if trial of preferred drug(s) is the only criterion that is not met for a given condition, and one of the following circumstances can be substantiated by the requesting provider, then trial of the preferred drug(s) will not be required.
 - The required prescription drug(s) is (are) contraindicated or will likely cause an adverse

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- reaction or physical or mental harm to the member;
 - The required prescription drug is expected to be ineffective based on the known clinical history and conditions and concurrent drug regimen;
 - The required prescription drug(s) was (were) previously tried while under the current or a previous health plan, or another prescription drug or drugs in the same pharmacologic class or with the same mechanism of action was (were) previously tried and such prescription drug(s) was (were) discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event;
 - The required prescription drug(s) is (are) not in the patient's best interest because it will likely cause a significant barrier to adherence to or compliance with the plan of care, will likely worsen a comorbid condition, or will likely decrease the ability to achieve or maintain reasonable functional ability in performing daily activities;
 - The individual is stable on the requested prescription drug. The medical profile of the individual (age, disease state, comorbidities), along with the rationale for deeming stability as it relates to standard medical practice and evidence-based practice protocols for the disease state will be taken into consideration.
 - The above criteria are not applicable to requests for brand name medications that have an AB rated generic. We can require a trial of an AB-rated generic equivalent prior to providing coverage for the equivalent brand name prescription drug.
4. When being administered by a health care professional in the office, certolizumab falls under the medical benefit.
 5. When self-administered, certolizumab falls under the pharmacy benefit.
 6. This policy is applicable to drugs that are included on a specific drug formulary. If a drug referenced in this policy is non-formulary, please reference the Coverage Exception Evaluation Policy for All Lines of Business Formularies policy for review guidelines.
 7. Involvement of the DIP joints, an asymmetric distribution of joint disease, spondyloarthritis, dactylitis, negative rheumatoid factor, sausage digits, new bone formation on radiographs, cutaneous findings, and the characteristic nail manifestations of psoriatic arthritis (nail pitting, onycholysis & other lesions, which include leukonychia, red spots in the lunula, and nail plate crumbling) all help to distinguish psoriatic arthritis from other inflammatory arthritis, including RA.
 8. Serious infections, sepsis, and cases of opportunistic infections, including fatalities, have been reported in patients receiving TNF blockers, including certolizumab
 9. Safety and effectiveness in children have not been established
 10. As observed with other TNF blockers, TB associated with the administration of certolizumab in clinical studies has been reported, including fatalities. All patients being considered for biologic therapy should be screened for latent tuberculosis infection, regardless of the presence of risk factors. Annual testing is recommended for patients who live, travel, or work in situations where tuberculosis exposure is likely.
 11. Use of TNF inhibitors has been associated with reactivation of hepatitis B virus (HBV) in patients who are chronic carriers of this virus. Patients at risk for HBV infection should be evaluated for prior evidence of HBV infection before initiating TNF inhibitor therapy.
 12. Malignancies have been reported in children and adolescents treated with TNF blockers. Cimzia is not indicated for use in children.
 13. Cases of worsening congestive heart failure (CHF) and new onset CHF have been reported with TNF blockers. Exercise caution when using certolizumab in patients who have heart failure and monitor them carefully. Use of anti-TNF agents is not recommended in patients with New York Heart Association class III or IV heart failure who have an ejection fraction of 50% or less

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14. Patients should not receive live attenuated herpes zoster vaccine while receiving anti-TNF therapy.
15. Certolizumab will not be authorized when used in combination with other biologics such as Kineret (anakinra), Orencia (abatacept), Rituxan (rituximab)

HCPCS: J0717 - Injection, certolizumab pegol, 1mg

NDC Codes:

50474070062 – Certolizumab 2 x 200 mg kit (lyophilized powder for reconstitution)
50474071079 – Certolizumab 2 x 200 mg/mL kit (prefilled syringe)
50474071081 – Certolizumab 6 x 200 mg/mL kit (prefilled syringe starter kit)

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates

UPDATES:

Date	Revision
1/20	Revised
6/19	Reviewed
5/19	Reviewed/Revision
6/18	Revision
1/18	Revision
1/17	Revision
1/16	Reviewed
2/14	Revision
12/13	Revision
11/13	Revision
2/13	Revision
2/12	Reviewed
1/11	Revised
12/09	Revised
5/2009	Created

REFERENCES:

1. Cimzia [package insert]. Smyrna, GA: UCB Inc.; Revised October 2016. Accessed December 2016.
2. American College of Rheumatology, Guidelines for the Management of Rheumatoid Arthritis - 2002 Update, Arthritis and Rheumatism, Vol. 46, No.2, February 2002, pg. 328-346.
3. Lichtenstein GR, Hanauer SB, Sandborn WJ, and the Practice Parameters Committee of the American College of Gastroenterology. Management of Crohn's Disease in Adults. ACG Practice Guidelines 2009. Amer J of Gastroenterology Accessed December 2016
4. Swaminath A and Kornbluth A. Optimizing Drug Therapy in Inflammatory Bowel Disease. Current Gastroenterology Reports. 2007;9:513-520
5. Velayos FS, Sandborn WJ. Positioning Biologic Therapy for Crohn's Disease and Ulcerative Colitis. Current Gastroenterology Reports. 2007;9:521-527
6. 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

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treatment of rheumatoid arthritis. *Arthritis care & research*. May 2012;64(5):625-639

7. Uptodate.com; Clinical manifestations and diagnosis of psoriatic arthritis. Literature review through October 2016; Accessed December 2016.
8. Singh, JA., Saag, K. et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Care & Research* October 2015.
9. Uptodate.com; Overview of the medical management of severe or refractory Crohn disease in adults. Literature review through October 2016; Accessed December 2016.