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: 05/2009
LAST REVIEW DATE: 12/06/2023

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. This drug policy applies to the following line/s of business:

Policy Application

Category:	☒ Commercial Group (e.g., EPO, HMO, POS, PPO)	☒ Medicare Advantage
	☒ On Exchange Qualified Health Plans (QHP)	☐ Medicare Part D
	☒ Off Exchange Direct Pay	☒ Essential Plan (EP)
	☒ Medicaid & Health and Recovery Plans (MMC/HARP)	☒ Child Health Plus (CHP)
	☐ Federal Employee Program (FEP)	☐ Ancillary Services
	☒ Dual Eligible Special Needs Plan (D-SNP)	

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. TNFα 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)
- treatment of adult patients with nonradiographic axial spondyloarthritis with objective signs of inflammation.
- 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. Must be 18 years of age or older **AND**
2. A diagnosis of ankylosing spondylitis established by a rheumatologist **AND**
3. Must be actively followed by and the drug prescribed by a rheumatologist **AND**
4. Presence of refractory disease defined by failure of at least **TWO** different NSAIDs given at maximum dosage for at least 1 month each **AND**
5. Step Therapy Applies –
    a. If self-administered, there must also be documentation of drug failure or serious side effects with **TWO** of the following: Enbrel, Humira/Cyltezo/Hadlima, Cosentyx, Xeljanz/XR, Rinvoq
    b. If office administered, there must also be documentation of drug failure or serious side effects with Inflectra/Avsola AND Simponi Aria
        i. Applies to all lines of business
6. Approved dosing is as follows:
    a. Initial dose of 400 mg (given as 2 subcutaneous injections of 200 mg) 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 200 mg every other week or 400 mg every 4 weeks

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

1. Must be 18 years of age or older **AND**
2. A diagnosis of non-radiographic axial spondylitis established by a rheumatologist **AND**
3. Must be actively followed by and the drug prescribed by a rheumatologist **AND**
4. Presence of refractory disease defined by failure of at least TWO different NSAIDs given as maximum dosage for at least 1 month each
5. Approved dosing is as follows:
    a. Initial dose of 400 mg (given as 2 subcutaneous injections of 200 mg) 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 400 mg every 4 weeks

C. Crohn's Disease

1. Must be 18 years of age or older **AND**
2. The patient must be actively followed by, and the drug prescribed by a gastroenterologist **AND**
3. The patient must have a diagnosis of moderately to severely active Crohn's Disease
    a. 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 **AND**
4. There must be documentation that azathioprine, 6-mercaptopurine, or methotrexate is ineffective, contraindicated or not tolerated **AND**
5. Step Therapy Applies –
    a. If self-administered, there must also be documentation of drug failure or serious side effects to Humira/Cyltezo/Hadlima
    b. If office administered, there must also be documentation of serious side effects or drug failure to **TWO** of the following: Inflectra/Avsola, Entyvio, Stelara
        i. Applies to all lines of business

6. Authorization period and dosing limitations:
    a. Initial dose 400 mg (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 400 mg every 4 weeks

D. Psoriatic Arthritis

1. Must be 18 years of age or older **AND**
2. A diagnosis of definitive psoriatic arthritis established by a Rheumatologist or Dermatologist **AND**
3. 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.
4. Member must be actively followed by, and the drug prescribed by a Rheumatologist or Dermatologist **AND**
5. Step Therapy Applies –
    a. If self-administered, there must also be documentation of drug failure or serious side effects to **TWO** of the following: Enbrel, Humira/Cyltezo/Hadlima, Stelara, Xeljanz/XR, Cosentyx, Otezla, Tremfya, Rinvoq, Skyrizi
    b. If office administered, there must also be documentation of drug failure or serious side effects to **TWO** of the following: Inflectra/Avsola, Stelara, Simponi Aria, Tremfya
        i. Applies to all lines of business
6. Cimzia dosing will be authorized as:
    a. Initial dose of 400 mg (given as 2 subcutaneous injections of 200 mg) 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 200 mg every other week (or 400 mg every 4 weeks)

E. Rheumatoid Arthritis

1. Must be 18 years of age or older **AND**
2. Member must be actively followed by, and the drug prescribed by a Rheumatologist **AND**
3. Member must have active moderate to severe rheumatoid arthritis **AND**
4. 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**
5. Step Therapy Applies –
    a. If self-administered, there must also be documentation of drug failure or serious side effects to **TWO** of the following: Actemra SC, Enbrel, Humira/Cyltezo/Hadlima, Xeljanz/Xeljanz XR, Rinvoq
    b. If office administered, there must also be documentation of drug failure or serious side effects to Inflectra/Avsola AND Simponi Aria
        i. Applies to all lines of business
6. Approved dosing is as follows:
    a. Initial dose of 400 mg (given as 2 subcutaneous injections of 200 mg) 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 200 mg every other week or 400 mg every 4 weeks
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. Must be 18 years of age or older **AND**
2. Member must be followed by a dermatologist or rheumatologist **AND**
3. Must have moderate to severe chronic plaque psoriasis that involves at least 10% body surface area. Consideration will be given to those who have less than 10% body surface area involvement but have severe disease of sensitive areas or areas causing significant disruption in normal activities (such as the hands, feet, face, genitalia) **AND**
4. Member must be a candidate for systemic therapy (i.e., acitretin, methotrexate, or cyclosporine) with a trial period of at least 3 months that resulted in an inadequate response (failure). A 3-month trial will not be required if the member experienced serious side effects during a trial of one of 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):
        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**
5. Step Therapy Applies –
    a. If <u>self-administered</u>, there also must be documentation drug failure or serious side effects to **TWO** of the following: Enbrel, Humira/Cyltezo/Hadlima, Stelara, Cosentyx, Otezla, Tremfya, Skyrizi
    b. If <u>office-administered</u>, there also must be documentation of drug failure or serious side effects to **TWO** of the following: Inflectra/Avsola, Stelara, Tremfya, Ilumya
        i. Applies to all lines of business
6. 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.

<u>APPROVAL TIME PERIODS:</u>

Line of Business	Rx Initial approval	Rx Recertification	Medical Initial approval	Medical Recertification
Commercial, Exchange, and SafetyNet (Medicaid, HARP, CHP, Essential Plan)	1 year	1 year	All sites of service: 1 year	All sites of service: 1 year
Medicare	Already defined in policy	Already defined in policy	All sites of service: 2 years	All sites of service: 2 years

POLICY GUIDELINES:

1. Utilization Management are contract dependent and coverage criteria may be dependent on the contract renewal date. Additionally, coverage of drugs listed in this policy are contract dependent. Refer to specific contract/benefit language for exclusions.
2. Not all contracts cover all Medical Infusible drugs. Refer to specific contract/benefit plan language for exclusions of Injectable Medications.
3. For members with Medicare Part B, medications with a National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) will be covered pursuant to the criteria outlined by the NCD and/or LCD. NCDs/LCDs for applicable medications can be found on the CMS website at https://www.cms.gov/medicare-coverage-database/search.aspx. Indications that have not been addressed by the applicable medication's LCD/NCD will be covered in accordance with criteria determined by the Health Plan (which may include review per the Health Plan's Off-Label Use of FDA Approved Drugs policy). Step therapy requirements may be imposed in addition to LCD/NCD requirements.
4. 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.
5. 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 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 rational 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.

6. When being administered by a health care professional in the office, certolizumab falls under the medical benefit.
7. When self-administered, certolizumab falls under the pharmacy benefit.
8. 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 Non-Formulary Medication Exception Review Policy for all Lines of Business (Pharmacy-69)
9. 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.
10. Serious infections, sepsis, and cases of opportunistic infections, including fatalities, have been reported in patients receiving TNF blockers, including certolizumab
11. Safety and effectiveness in children have not been established
12. 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.
13. 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.
14. Malignancies have been reported in children and adolescents treated with TNF blockers. Cimzia is not indicated for use in children.
15. 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
16. Patients should not receive live attenuated herpes zoster vaccine while receiving anti-TNF therapy.
17. Certolizumab will not be authorized when used in combination with other biologics such as Kineret (anakinra), Orencia (abatacept), a rituximab containing product.
18. Concurrent use of Inflammatory Agents
    a. Cimzia as well as other immunomodulating therapies or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs) (Humira/Cyltezo/Hadlima, Enbrel, Stelara, Remicade, biosimilars, etc.) should not be administered in combination with another biologic or targeted synthetic DMARD used for an inflammatory condition. Combination therapy is generally not recommended due to the added risk of immunosuppression, potential for a higher rate of adverse effects, and lack of evidence for additive therapy. NOTE: This does NOT exclude the use of conventional synthetic DMARDs (e.g., MTX, leflunomide, hydroxychloroquine, and sulfasalazine) in combination with biologics and targeted synthetic DMARDs.
    b. Requests for the concurrent use of inflammatory agents will be evaluated for safety and efficacy and are subject to off-label review.
    c. Otezla in combination with biologic DMARD therapy (such as adalimumab, Enbrel, Cosentyx, Xeljanz etc.) is not FDA approved or supported with a high level of clinically valid medical evidence for the treatment of plaque psoriasis or psoriatic arthritis. Therefore, these requests are considered combination therapy and are considered not medically necessary.

Pharmacy Management Drug Policy
Cimzia® (certolizumab pegol)

HCPCS: **J0717 - Injection, certolizumab pegol, 1mg**

NDCs:

NDC	Package Contents	Quantity Limit per 28 days (Rx Benefit)
50474 0700 62	2-200 mg vials (lyophilized powder for reconstitution)	N/A
50474 0710 79	2-200 mg/mL prefilled syringes (2-200 mg/mL prefilled syringes/carton; 1 carton/package)	1 package (1 carton)
50474 0710 81	3 x 2-200 mg/mL cartons (2-200 mg/mL prefilled syringes/carton; 3 cartons/package)	1 package (3 cartons)

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
12/06/2023	Revised
09/01/2023	Revised
08/24/2023	Reviewed / P&T Committee Approval
03/15/2023	Revised
01/01/2023	Revised
9/22/2022	P&T Committee Approval
04/2022	Revised
02/2022	Revised
09/2021	Reviewed / P&T Committee Approval
01/2021	Revised
11/2020	Revised
10/2020	Revised
09/16/2020	P&T Approval
08/2020	Revised
06/2020	Revised
02/2020	Revised
01/2020	Revised
09/2019	P&T Approval
06/2019	Reviewed
05/2019	Reviewed/Revision
06/2018	Revision
01/2018	Revision
01/2017	Revision
01/2016	Reviewed
02/2014	Revision
12/2013	Revision
11/2013	Revision
02/2013	Revision
02/2012	Reviewed
01/2011	Revised

12/2009	Revised
05/2009	Created

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