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: 11/19/2025

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)
- the 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
- the treatment of active polyarticular juvenile idiopathic arthritis in patients ≥2 years of age.

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. Must have a diagnosis of Ankylosing Spondylitis **AND**
3. Must be prescribed by or in consultation with a Rheumatologist **AND**
4. Must have refractory disease defined by failure of or intolerance to at least **TWO** different NSAIDS at maximum strength for at least 1 month each **AND**

5. Must also meet the following:
   a. If self-administered, there must also be documentation of drug failure or serious side effects with **TWO** of the following: Enbrel, Humira/Simlandi/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 at least 18 years of age **AND**
2. Must have a diagnosis of non-radiographic axial spondylitis **AND**
3. Must be prescribed by or in consultation with a Rheumatologist **AND**
4. Must have refractory disease defined by failure of or intolerance to at least **TWO** different NSAIDS at maximum strength 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. Must be prescribed by or in consultation with a Gastroenterologist **AND**
3. The patient must have a diagnosis of moderately to severely active Crohn's Disease
4. There must be documentation that azathioprine, 6-mercaptopurine, or methotrexate is ineffective, contraindicated or not tolerated.
   a. Treatment with a biologic medication as first-line therapy will be assessed on a case-by-case basis through a letter of medical necessity and clinical progress notes based on severity of the disease (such as but not limited to enterocutaneous [perianal or abdominal] fistulas, rectovaginal fistulas, ileocolonic resection) **AND**
5. Must also meet the following:
   a. If self-administered, there must also be documentation of drug failure or serious side effects to Humira/Simlandi/ 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/Selarsdi/Yesintek, Tremfya
      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. Must be prescribed by or in consultation with a Dermatologist or Rheumatologist **AND**
3. Must have a diagnosis of active Psoriatic Arthritis
4. Must also meet the following:
   a. If self-administered, there must also be documentation of drug failure or serious side effects to **TWO** of the following: Enbrel, Humira/Simlandi/ Hadlima, Stelara/Selarsdi/Yesintek, 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/Selarsdi/Yesintek, Simponi Aria, Tremfya
      i. Applies to all lines of business
5. 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. Must be prescribed by or in consultation with a Rheumatologist **AND**
3. Member must have a diagnosis of moderately to severely active **Rheumatoid Arthritis AND**
4. 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. Must also meet the following:
   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/Simlandi/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

F. Plaque Psoriasis
1. Must be 18 years of age or older **AND**
2. Must be prescribed by or in consultation with 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. The patient must be a candidate for systemic therapy or phototherapy and meet for **ONE** of the following (**a or b**)
   a. The patient must have had a 3-month trial of systemic therapy (i.e., acitretin, methotrexate, or cyclosporine) 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 aforementioned agents **OR**
   b. The patient must have had a 3-month trial of Ultraviolet B (UVB) Phototherapy or Psoralen Ultraviolet A (PUVA) Phototherapy that resulted in an inadequate response (failure)
5. Must also meet the following:
   a. If self-administered, there also must be documentation drug failure or serious side effects to **TWO** of the following: Enbrel, Humira/Simlandi/Hadlima, Stelara/Selarsdi/Yesintek, Cosentyx, Otezla, Tremfya, Skyrizi, Sotyktu
   b. If office-administered, there also must be documentation of drug failure or serious side effects to **TWO** of the following: Inflectra/Avsola, Stelara/Selarsdi/Yesintek, 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.

G. Polyarticular Juvenile Idiopathic Arthritis (pJIA)

1. Must be 2 years or older
2. Must be prescribed by or in consultation with a Rheumatologist **AND**
3. Must have a contraindication to, have failed to respond to, or must be intolerant to treatment with a disease-modifying antirheumatic drug (DMARD) (such as methotrexate, leflunomide, sulfasalazine), NSAID, analgesic, or corticosteroid
   a. Patients starting on Cimzia concurrently with methotrexate, sulfasalazine, or leflunomide will not be subject to the above requirement.
4. If self-administered, the patient must weigh at least 40 kg (88 lbs) and must also have a documented drug failure or serious side effects to **TWO** of the following agents: Actemra SC, Enbrel, Humira/Simlandi/Hadlima, Xeljanz, Rinvoq
5. If office administered, treatment with IV Cimzia will require failure or serious side effects with Simponi Aria for a diagnosis of pJIA
6. The recommended dose of Cimzia for patients 2 years and older with pJIA is based on weight:
   a. 10 kg (22 lbs) to less than 20 kg (44 lbs): Loading dose of 100mg at Week 0, 2 and 4, followed by maintenance dose of 50mg every 2 weeks beginning at Week 6
   b. 20 kg (44 lbs) to less than 40 kg (88 lbs): Loading dose of 200mg at Week 0, 2 and 4, followed by maintenance dose of 100mg every 2 weeks beginning at Week 6
   c. Greater than or equal to 40 kg (88 lbs): Loading dose of 400mg at Week 0, 2 and 4, followed by maintenance dose of 200mg every 2 weeks beginning at Week 6
   d. There is no dosage form for Cimzia that allows for patient self-administration for doses below 200 mg. Doses less than 200 mg require administration by a health care professional using the vial kit.

APPROVAL TIME PERIODS:

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. This policy does not apply to Medicare Part D and D-SNP pharmacy benefits. The drugs in this policy may apply to all other lines of business including Medicare Advantage.
4. For members with Medicare Advantage, 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.

5. 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. Clinical documentation must be submitted for each request (initial and recertification) unless otherwise specified (e.g., provider attestation required). Supporting documentation includes, but is not limited to, progress notes documenting previous treatments/treatment history, diagnostic testing, laboratory test results, genetic testing/biomarker results, imaging and other objective or subjective measures of benefit which support 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.
6. 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.
7. When being administered by a health care professional in the office, certolizumab falls under the medical benefit.
8. When self-administered, certolizumab falls under the pharmacy benefit.
9. 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)
10. **Concurrent use of Inflammatory Agents**
    a. Cimzia as well as other immunomodulating therapies or Targeted Synthetic Disease-Modifying

Antirheumatic Drugs (DMARDs) (Humira/Simlandi/ Hadlima, Enbrel, ustekinumab, 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.

11. All requests will be reviewed to ensure they are being used for an appropriate indication and may be subject to an off-label review in accordance with our Off-Label Use of FDA Approved Drugs Policy (Pharmacy-32).
12. All utilization management requirements outlined in this policy are compliant with applicable New York State insurance laws and regulations. Policies will be reviewed and updated as necessary to ensure ongoing compliance with all state and federally mandated coverage requirements.
13. Manufacturers may either discontinue participation in, or may not participate in, the Medicaid Drug Rebate Program (MDRP). Under New York State Medicaid requirements, physician-administered drugs must be produced by manufacturers that participate in the MDRP. Products made by manufacturers that do not participate in the MDRP will not be covered under Medicaid Managed Care/HARP lines of business. Drug coverage will not be available for any product from a non-participating manufacturer. For a complete list of New/Reinstated & Terminated Labelers please visit: https://www.medicaid.gov/medicaid/prescriptiondrugs/medicaid-drug-rebate-program/newreinstated-terminated-labeler-information/index.html

HCPCS: J0717 - Injection, certolizumab pegol, 1mg

NDCs:

NDC	Package Contents	Quantity Limit per 28 days (Rx Benefit)
50474 0700 62	2 x 200 mg vials (lyophilized powder for reconstitution)	N/A
50474 0750 10	1 x 200mg/mL prefilled syringe (1-200mg/mL prefilled syringe/carton; 1 carton/package)	2 packages (2 cartons)
50474 0710 79	2 x 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
11/19/2025	Revised
11/13/2025	Reviewed / P&T Committee Approval

10/13/2025	Revised
10/01/2025	Revised
04/16/2025	Revised
03/06/2025	Revised
02/17/2025	Revised
01/01/2025	Revised
10/01/2024	Revised
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08/15/2024	Reviewed / P&T Committee Approval
06/24/2024	Revised
06/04/2024	Revised
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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