Cimzia (certolizumab pegol)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Cimzia (certolizumab pegol) 200 mg/mL vial kit*‡	1 vial kit (2 x 200 mg vials) per 28 days
Cimzia (certolizumab pegol) 200 mg/mL prefilled syringe kit*‡	1 syringe kit (2 x 200 mg/mL syringes) per 28 days
Cimzia (certolizumab pegol) 200 mg/mL starter kit*	1 starter kit (6 x 200 mg/mL syringes) (28 day supply, one time fill)

*Initiation of therapy for Crohn's Disease (CD), Rheumatoid Arthritis (RA), Psoriatic Arthritis (PsA), Plaque Psoriasis (Psoriasis Vulgaris) (Ps), Ankylosing Spondylitis (AS), or non-radiographic axial spondyloarthritis (nr-axSpA): May approve one starter kit OR up to three vial kits (2 x 200 mg vials per kit) or syringe kits (2 x 200 mg/mL syringes per kit) in the first month (28 days) of treatment.

‡In the treatment of Plaque Psoriasis (Ps): May approve up to an additional 1 vial kit (2 x 200 mg vials) or syringe kit (2 x 200 mg/mL syringes) every 28 days.

‡For CD, may approve increased dosing, up to 2 syringe/vial kits every 4 weeks (i.e. four total syringes/vials every 4 weeks) if the following criteria are met:

A. Individual has been treated with standard maintenance dosing (i.e. 400 mg every 4 weeks) for *at least* 4 doses or 16 weeks; **AND**
B. The increased dosing is being prescribed by or in consultation with a gastroenterologist; **AND**
C. Individual initially achieved an adequate response to standard maintenance dosing but has subsequently lost response, as determined by the prescriber; **OR**
D. Individual partially responded but had an inadequate response to standard maintenance dosing as determined by the prescriber; **AND**
E. Symptoms, if present, are not due to active infections or any other gastrointestinal disorder other than the primary disease; **AND**
F. Requested dosing does not exceed up to 2 syringe/vial kits every 4 weeks.

Initial approval duration for increased dosing for CD: 16 weeks

‡Requests for continued escalated dosing for CD may be approved if the following criteria are met:

A. Requested dosing does not exceed up to 2 syringe/vial kits every 4 weeks; **AND**
B. Individual has subsequently regained response or achieved adequate response following increased dosing, as shown by improvement in signs and symptoms of the disease (including but not limited to reduction in stool frequency/bloody stools, improvement abdominal pain, or endoscopic response); **AND**
C. Individual is not experiencing unacceptable adverse effects from increased dosing; **AND**
D. Individual will be assessed regularly for dose de-escalation.

Continued approval duration for increased dosing for CD: 6 months

‡For CD, Increased dosing may not be approved for the following:
A. Individual has had no response to Cimzia at standard maintenance dosing (i.e. 400 mg every 4 weeks); **OR**

Individual is requesting dose escalation in absence of signs and symptoms of the disease (for example, requesting based on results of therapeutic drug level or anti-drug antibody testing alone).

APPROVAL CRITERIA

Requests for Cimzia (certolizumab pegol) may be approved for the following:

I. Crohn's disease (CD) when each of the following criteria are met:
A. Individual is 18 years of age or older with moderate to severe CD; **AND**
B. Individual has had an inadequate response to or is intolerant of conventional therapy (such as systemic corticosteroids, or immunosuppressants [such as thiopurines or methotrexate]); **OR**
C. Individual has a contraindication to systemic corticosteroids or thiopurines or methotrexate;
AND
D. Documentation is provided that individual has had a trial and inadequate response or intolerance to TWO (2) preferred biologic agents [Current preferred biologics include – adalimumab-adbm, Humira (adalimumab) and Stelara (ustekinumab)]. Medication samples/coupons/discount cards are excluded from consideration as a trial.;
AND
1. Documentation is provided describing the nature of the inadequate response or intolerance for each product tried;
OR
2. Documentation is provided that a completed FDA MedWatch Adverse Event Reporting Form has been submitted to the FDA for each product tried;

OR
E. Documentation is provided that individual has been receiving and is maintained on a stable dose of Cimzia

F. (certolizumab pegol). Medication samples/coupons/discount cards are excluded from consideration as a trial; **OR**
G. Documentation is provided that individual is pregnant or planning on becoming pregnant;

OR

II. Rheumatoid arthritis (RA) when each of the following criteria are met:
A. Individual is 18 years of age or older with moderate to severe RA; **AND**
B. Documentation is provided that individual has had an inadequate response to methotrexate titrated to maximally tolerated dose (ACR 2021); **OR**
C. Documentation is provided that if methotrexate is not tolerated, individual has had an inadequate response to or is intolerant of other conventional therapy (sulfasalazine, leflunomide, or hydroxychloroquine); **OR**
C. Documentation is provided that individual has a contraindication to methotrexate, sulfasalazine, leflunomide, and hydroxychloroquine;
AND
D. Documentation is provided that individual has had a trial and inadequate response or intolerance to TWO (2) preferred biologic agents [Current preferred biologics include – adalimumab-adbm, Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib)*, or Simponi (golimumab)]. Medication samples/coupons/discount cards are excluded from consideration as a trial.;
AND
1. Documentation is provided describing the nature of the inadequate response or intolerance for each product tried;
OR
2. Documentation is provided that a completed FDA MedWatch Adverse Event Reporting Form has been submitted to the FDA for each product tried;

OR

E. Documenation is provided that individual has been receiving and is maintained on a stable dose of Cimzia (certolizumab pegol). Medication samples/coupons/discount cards are excluded from consideration as a trial.; **OR**
F. Documentation is provided that individual is pregnant or planning on becoming pregnant; **OR**

*Note: Rinvoq is the preferred Janus Kinase (JAK) inhibitor. JAK inhibitor clinical criteria require a trial and inadequate response or intolerance to one or more tumor necrosis factor (TNF) antagonist agents**.**

OR

III. Ankylosing spondylitis (AS) when each of the following criteria are met:
A. Individual is 18 years of age or older with moderate to severe AS; **AND**
B. Individual has had an inadequate response to or is intolerant of conventional therapy [such as NSAIDs or nonbiologic disease-modifying antirheumatic drugs (DMARDs) (such as sulfasalazine)];
OR
C. Individual has a contraindication to NSAIDs or sulfasalazine;

AND

D. Documentation is provided that individual has had a trial and inadequate response or intolerance to TWO (2) preferred biologic agents [Current preferred biologics include – adalimumab-adbm, Cosentyx (secukinumab)*, Enbrel (etanercept), Humira (adalimumab), or Simponi (golimumab)]. Medication samples/coupons/discount cards are excluded from consideration as a trial.;

AND

1. Documentation is provided describing the nature of the inadequate response or intolerance for each product tried;

OR

2. Documentation is provided that a completed FDA MedWatch Adverse Event Reporting Form has been submitted to the FDA for each product tried;

OR

E. Documentation is provided that individual has been receiving and is maintained on a stable dose of Cimzia (certolizumab pegol). Medication samples/coupons/discount cards are excluded from consideration as a trial.; **OR**

F. Documentation is provided that individual is pregnant or planning on becoming pregnant; **OR**

*Note: Rinvoq is the preferred Janus Kinase (JAK) inhibitor. JAK inhibitor clinical criteria require a trial and inadequate response or intolerance to one or more tumor necrosis factor (TNF) antagonist agents**.**

OR

III. Non-radiographic axial spondyloarthritis (nr-axSpA) when each of the following criteria are met:

A. Individual is 18 years of age or older with moderate to severe nr-axSpA; **AND**

B. Individual has had an inadequate response to or is intolerant of conventional therapy [such as NSAIDs or nonbiologic disease-modifying antirheumatic drugs (DMARDs) (such as sulfasalazine)] (ACR 2019);

OR

C. Individual has a contraindication to NSAIDs or sulfasalazine;

AND

D. Documentation is provided that individual has had a trial and inadequate response or intolerance to ONE (1) preferred biologic agents [Current preferred biologic includes – Cosentyx (secukinumab)*]. Medication samples/coupons/discount cards are excluded from consideration as a trial,;

AND

1. Documentation is provided describing the nature of the inadequate response or intolerance for each product tried;

OR

2. Documentation is provided that a completed FDA MedWatch Adverse Event Reporting Form has been submitted to the FDA for each product tried;

OR

E. Documentation is provided that individual has been receiving and is maintained on a stable dose of Cimzia (certolizumab pegol). Medication samples/coupons/discount cards are excluded from consideration as a trial.; **OR**
F. Documentation is provided that individual is pregnant or planning on becoming pregnant;

OR

V. Psoriatic arthritis (PsA) when each of the following criteria are met:
   A. Individual is 18 years of age or older with moderate to severe PsA; **AND**
   B. Individual has had an inadequate response to or is intolerant of conventional therapy [nonbiologic disease-modifying antirheumatic drugs (DMARDs) (such as methotrexate, sulfasalazine, cyclosporine, or leflunomide)]; **OR**
   C. Individual has a contraindication to methotrexate, sulfasalazine, cyclosporine, and leflunomide;
      AND
   D. Documentation is provided that individual has had a trial and inadequate response or intolerance to TWO (2) preferred biologic agents [Current preferred biologics include – **a**dalimumab-adbm, Cosentyx (secukinumab)*, Enbrel (etanercept), Humira (adalimumab), Otezla (apremilast), Simponi (golimumab), Stelara (ustekinumab), Tremfya (guselkumab)*]. Medication samples/coupons/discount cards are excluded from consideration as a trial.;
      AND
      1. Documentation is provided describing the nature of the inadequate response or intolerance for each product tried;
         OR
      2. Documentation is provided that a completed FDA MedWatch Adverse Event Reporting Form has been submitted to the FDA for each product tried;

   OR

   E. Documentation is provided that individual has been receiving and is maintained on a stable dose of Cimzia (certolizumab pegol). Medication samples/coupons/discount cards are excluded from consideration as a trial.; **OR**
   F. Documentation is provided that individual is pregnant or planning on becoming pregnant; **OR**

OR

VI. Plaque psoriasis (Ps) (Psoriasis vulgaris) when each of the following criteria are met:
   A. Individual is 18 years of age or older with chronic moderate to severe (that is, extensive or disabling) plaque Ps (psoriasis vulgaris) with either of the following (AAD 2011):
      1. Plaque Ps (Psoriasis vulgaris) involving greater than five percent (5%) body surface area (BSA); **OR**
      2. Plaque Ps (Psoriasis vulgaris) involving less than or equal to five percent (5%) BSA involving sensitive areas or areas that significantly

impact daily function (such as palms, soles of feet, head/neck, or genitalia);

AND

B. Individual has had an inadequate response to or is intolerant of phototherapy or other systemic therapy (such as acitretin, cyclosporine, or methotrexate); **OR**
C. Individual has a contraindication to phototherapy, acitretin, cyclosporine, and methotrexate;

AND

D. Documentation is provided that individual has had a trial and inadequate response or intolerance to TWO (2) preferred biologic agents [Current preferred biologics include – adalimumab-adbm, Cosentyx (secukinumab)*, Enbrel (etanercept), Humira (adalimumab), Otezla (apremilast), Stelara (ustekinumab), Tremfya (guselkumab)*]. Medication samples/coupons/discount cards are excluded from consideration as a trial.;

AND

1. Documentation is provided describing the nature of the inadequate response or intolerance for each product tried;

OR

2. Documentation is provided that a completed FDA MedWatch Adverse Event Reporting Form has been submitted to the FDA for each product tried;

OR

E. Documentation is provided that individual has been receiving and is maintained on a stable dose of Cimzia (certolizumab pegol). Medication samples/coupons/discount cards are excluded from consideration as a trial.; **OR**
F. Documentation is provided that individual is pregnant or planning on becoming pregnant; **OR**

VII. Immune checkpoint inhibitor therapy-related toxicities in an individual with any of the following conditions (NCCN 2A):
   A. Moderate to Severe inflammatory arthritis unresponsive to corticosteroids or nonbiologic DMARDs.

*Note - Trial of Cosentyx (secukinumab) does not apply in states where not on formulary (CA, CO). Prior trial of Tremfya (guselkumab) not required in states where not covered (CA, CO, GA, IN, KY, ME, MO, NH, NY, OH, VA, WI]. Prior trial of Rinvoq (upadacitinib) not required in states where not covered (CA, CO, NH, NY, WI).

Continuation requests for Cimzia (certolizumab pegol) may be approved if the following criteria are met:

I. Documentation is provided that individual has been receiving and is maintained on a stable dose of Cimzia (certolizumab pegol). Medication samples/coupons/discount cards are excluded from consideration as a trial.; **AND**
II. There is clinically significant improvement or stabilization in clinical signs and symptoms of the disease.

Requests for Cimzia (certolizumab pegol) may **not** be approved for the following:

I. In combination with oral or topical JAK inhibitors, ozanimod, apremilast, etrasimod, deucravacitinib, or any of the following biologic immunomodulators: Other TNF antagonists, IL-23 inhibitors, IL-17 inhibitors, IL-6 inhibitors, IL-1 inhibitors, vedolizumab, ustekinumab, abatacept, rituximab, or natalizumab; **OR**
II. Tuberculosis, other active serious infections, or a history of recurrent infections [repeat testing not required for ongoing authorization]; **OR**
III. If initiating therapy, individual has not had a tuberculin skin (TST), or a Centers for Disease control (CDC-) and Prevention -recommended equivalent, to evaluate for latent tuberculosis (unless switching therapy from another targeted immune modulator and no new risk factors); **OR**
IV. When the above criteria are not met and for all other indications.

Note:
TNFi have black box warnings for serious infections and malignancy. Individuals treated with TNFi are at increased risk for developing serious infections that may lead to hospitalization or death. Most individuals who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids. TNFi should be discontinued if an individual develops a serious infection or sepsis. Individuals should be tested for latent tuberculosis (TB) before TNFi use and during therapy. Treatment for latent TB should be initiated prior to TNFi use. Risks and benefits of TNFi should be carefully considered prior to initiation of therapy in individuals with chronic or recurrent infection. Lymphoma and other malignancies have been reported in children and adolescents treated with TNFi. Postmarketing cases of hepatosplenic T-cell lymphoma (HSTCL) have been reported in individuals treated with TNFi. Almost all cases had received treatment with azathioprine or 6-mercaptopurine concomitantly with a TNFi at or prior to diagnosis. It is uncertain whether HSTCL is related to the use of a TNFi or a TNFi in combination with these other immunosuppressants.

Key References:

1. Brunner HI, Ruperto N, Tzaribachev N, et al. Subcutaneous golimumab for children with active polyarticular-course juvenile idiopathic arthritis: results of a multicentre, double-blind, randomised-withdrawal trial. Ann Rheum Dis. 2018; 77(1):21-29.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: October 20, 2022.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
5. NCCN Drugs & Biologics Compendium (NCCN Compendium®) 2022 National Comprehensive Cancer Network, Inc. Available at: NCCN.org. Updated periodically. Accessed on: October 14, 2022.
6. Centers for Disease Control and Prevention (CDC). Tuberculosis (TB). Available at: https://www.cdc.gov/tb/topic/basics/risk.htm. Last updated: March 18, 2016. Accessed October 28, 2022.

7. Fraenkel L, Bathon JM, England BR et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care & Research. 2021;73(7):924-939.
8. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. *J Am Acad Dermatol*. 2019; 80: 1029-72.
9. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis Rheum. 2019; 71(1): 5-32.
10. Feuerstein JD, Ho EY, Shmidt E et al. American Gastroenterological Association Clinical Practice Guidelines on the Medical Management of Moderate to Severe Luminal and Perianal Fistulizing Crohn's Disease. Gastroenterology 2021; 160:2496-2508.
11. Ward MM. Deodhar A, Gensler LS, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/ Spondyloarthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. Arthritis Rheumatol. 2019; 71(10):1599-1613.
12. Cohen SB, Alonso-Ruiz A, Klimiuk PA, et al. Similar efficacy, safety and immunogenicity of adalimumab biosimilar BI 695501 and Humira reference product in patients with moderately to severely active rheumatoid arthritis: results from the phase III randomized VOLTAIRE-RA equivalence study. Ann Rheum Dis 2018; 77: 914–21.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.