Cimzia (certolizumab pegol)

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

Medications	Quantity Limit
Cimzia (certolizumab pegol) 200 mg/mL vial kit [2 vials per kit]^‡	2 vials per 28 days
Cimzia (certolizumab pegol) 200 mg/mL prefilled syringe kit [2-pack and 1-pack]^‡	2 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: May approve one starter kit OR up to six total vials/syringes (200mg/mL) in the first month (28 days) of treatment.

‡In the treatment of Plaque Psoriasis (Ps): May approve up to an additional two vials/syringes (200mg/mL) every 28 days.

‡For CD, may approve increased dosing, up to 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 four total syringes/vials 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 four total syringes/vials 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: 1 year

‡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**
B. 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. Documentation is provided that individual has had a trial and inadequate response or intolerance to TWO (2) preferred agents [Current preferred agents include – preferred adalimumab (Reference product Humira), Skyrizi (risankizumab-rzaa), Tremfya (guselkumab)*, Stelara (ustekinumab)]. A trial of multiple products with the same active ingredient counts as a trial of ONE preferred agent. Medication samples/coupons/discount cards are excluded from consideration as a trial.; **AND**
A. Documentation is provided describing the nature of the inadequate response or intolerance for each product tried; **OR**
B. Documentation is provided that a completed FDA MedWatch Adverse Event Reporting Form has been submitted to the FDA for each product tried;

OR
C. Documentation is provided that individual is currently on Cimzia (certolizumab pegol). Medication samples/coupons/discount cards are excluded from consideration as a trial; **OR**
D. Documentation is provided that individual is pregnant or planning on becoming pregnant; **OR**
E. Documentation is provided for why the individual is unable to use ALL preferred agents (or all remaining preferred agents if individual has tried any preferred agent) due to one of the following:
1. The individual is subject to a warning or contraindication that appears in

the labeling of ALL preferred products and is not included in the labeling of Cimzia (certolizumab pegol); **OR**

2. None of the preferred products have activity against the individual's concomitant clinical condition which is covered by Cimzia (certolizumab pegol);

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. Individual has had an inadequate response to methotrexate titrated to maximally tolerated dose (ACR 2021); **OR**

C. If methotrexate is not tolerated, individual has had an inadequate response to or is intolerant of other conventional therapy (sulfasalazine, leflunomide, or hydroxychloroquine); **OR**

D. Individual has a contraindication to methotrexate, sulfasalazine, leflunomide, and hydroxychloroquine;
AND

E. Documentation is provided that individual has had a trial and inadequate response or intolerance to TWO (2) preferred agents [Current preferred agents include – preferred adalimumab (Reference product Humira), Enbrel (etanercept), Simponi (golimumab)]¥. A trial of multiple products with the same active ingredient counts as a trial of ONE preferred agent. 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

F. Documenation is provided that individual is currently on Cimzia (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**
OR

H. Documentation is provided for why the individual is unable to use ALL preferred agents (or all remaining preferred agents if individual has tried any preferred agent) due to one of the following:

1. The individual is subject to a warning or contraindication that appears in the labeling of ALL preferred products and is not included in the labeling of Cimzia (certolizumab pegol); **OR**
2. None of the preferred products have activity against the individual's concomitant clinical condition which is covered by Cimzia (certolizumab pegol);

¥Note: Rinvoq is the preferred Janus Kinase (JAK) inhibitor.

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 agents [Current preferred agents include – preferred adalimumab (Reference product Humira), Cosentyx (secukinumab), Enbrel (etanercept), or Simponi (golimumab)]. A trial of multiple products with the same active ingredient counts as a trial of ONE preferred agent. 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 is currently on 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
   G. Documentation is provided for why the individual is unable to use ALL preferred agents (or all remaining preferred agents if individual has tried any preferred agent) due to one of the following:
      1. The individual is subject to a warning or contraindication that appears in the labeling of ALL preferred products and is not included in the labeling of Cimzia (certolizumab pegol); **OR**
      2. None of the preferred products have activity against the individual's concomitant clinical condition which is covered by Cimzia (certolizumab pegol);

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 agent [Current preferred agent 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 is currently on 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

G. Documentation is provided for why the individual is unable to use Cosentyx (secukinumab) due to one of the following:

1. The individual is subject to a warning or contraindication that appears in the labeling of Cosentyx (secukinumab) and is not included in the labeling of Cimzia (certolizumab pegol); **OR**
2. Cosentyx (secukinumab) does not have activity against the individual's concomitant clinical condition which is covered by Cimzia (certolizumab pegol);

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 agents [Current preferred agents include –

preferred adalimumab (Reference product Humira), Cosentyx (secukinumab), Enbrel (etanercept), Otezla (apremilast), Simponi (golimumab), Skyrizi (risankizumab-rzaa), Stelara (ustekinumab), Tremfya (guselkumab)*]. A trial of multiple products with the same active ingredient counts as a trial of ONE preferred agent. 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 is currently on 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

G. Documentation is provided for why the individual is unable to use ALL preferred agents (or all remaining preferred agents if individual has tried any preferred agent) due to one of the following:
   1. The individual is subject to a warning or contraindication that appears in the labeling of ALL preferred products and is not included in the labeling of Cimzia (certolizumab pegol); **OR**
   2. None of the preferred products have activity against the individual's concomitant clinical condition which is covered by Cimzia (certolizumab pegol);

OR

III. Polyarticular juvenile idiopathic arthritis (PJIA) when each of the following criteria are met:

A. Individual is 2 years of age or older with moderate to severe PJIA; **AND**

B. Individual has had an inadequate response to or is intolerant of conventional therapy [nonbiologic DMARDS (such as methotrexate)] (ACR 2019); **OR**

C. Individual has a contraindication to methotrexate;

AND

D. Documentation is provided that individual has had a trial and inadequate response or intolerance to TWO (2) preferred agents [Current preferred agents include – preferred adalimumab (Reference product Humira), Enbrel (etanercept)] unless the following criteria is met. A trial of multiple products with the same active ingredient counts as a trial of ONE preferred agent. 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 is currently on 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

G. Documentation is provided for why the individual is unable to use ALL preferred agents (or all remaining preferred agents if individual has tried any preferred agent) due to one of the following:
    1. The individual is subject to a warning or contraindication that appears in the labeling of ALL preferred products and is not included in the labeling of Cimzia (certolizumab pegol); **OR**
    2. None of the preferred products have activity against the individual's concomitant clinical condition which is covered by Cimzia (certolizumab pegol);

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 five percent (5%) body surface area (BSA) or greater; **OR**
    2. Plaque Ps (Psoriasis vulgaris) involving less than 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 agents [Current preferred agents include – preferred adalimumab (Reference product Humira), Cosentyx (secukinumab), Enbrel (etanercept), Otezla (apremilast), Skyrizi (risankizumab-rzaa), Stelara (ustekinumab), Tremfya (guselkumab)*]. A trial of multiple products with the same active ingredient counts as a trial of ONE preferred agent. 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 is currently on 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

G. Documentation is provided for why the individual is unable to use ALL preferred agents (or all remaining preferred agents if individual has tried any preferred agent) due to one of the following:
   1. The individual is subject to a warning or contraindication that appears in the labeling of ALL preferred products and is not included in the labeling of Cimzia (certolizumab pegol); **OR**
   2. None of the preferred products have activity against the individual's concomitant clinical condition which is covered by Cimzia (certolizumab pegol);

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 preferred products does not apply in states where not on formulary. Tremfya (guselkumab) non-formulary (NY).

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.

Key References:

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2. 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.
3. Centers for Disease Control and Prevention (CDC). Tuberculosis (TB). Available at: https://www.cdc.gov/tb/risk-factors/?CDC_AAref_Val=https://www.cdc.gov/tb/topic/basics/risk.htm. Last updated: March 12, 2024.
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5. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: October 1, 2024.
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8. 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.
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10. 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.
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12. Onel KB, Horton DB, Lovell DJ, et al. 2021 American College of Rheumatology Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Oligoarthritis, Temporomandibular Joint Arthritis, and Systemic Juvenile Idiopathic Arthritis. Arthritis Rheum. 2022; 74(4):553-569.
13. Ringold S, Angeles-Han ST, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Non-Systemic Polyarthritis, Sacroiliitis, and Enthesitis. Arthritis Rheum. 2019; 71(6):846-863.
14. 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.
15. 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.

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