CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Cimzia (certolizumab pegol)
BENEFIT TYPE	Medical or Pharmacy
STATUS	Prior Authorization Required

Cimzia is a tumor necrosis factor (TNF) alpha-inhibitor initially approved by the FDA in 2008 for adults with moderate to severe Crohn's disease. Since that time, Cimzia has been approved for additional indications: rheumatoid arthritis, psoriatic arthritis, plaque psoriasis, ankylosing spondylitis, non-radiographic axial spondyloarthritis, and polyarticular juvenile idiopathic arthritis.

Cimzia (certolizumab pegol) will be considered for coverage when the following criteria are met:

Ankylosing Spondylitis (AS) or Non-Radiographic Axial Spondyloarthritis (nr-axSpA)

Note: Diagnosis of axial spondyloarthritis (axSpA) is also accepted. SpA comprises of 2 subtypes – ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA).

For **initial** authorization:
1. Member must be 18 years of age or older; AND
2. Member has a documented diagnosis of active AS, axSpA, or nr-axSpA; AND
3. Medication must be prescribed by or in consultation with a rheumatologist; AND
4. Member shows **ONE** of the following signs or symptoms of inflammation:
   a) Elevated serum C-reactive protein (CRP);
   b) Sacroiliitis on magnetic resonance imaging (MRI); AND
5. Member has had a trial and failure of **TWO** NSAIDs for 14 days each, taken at the maximum recommended dosages; AND
6. Member has tried and failed, or unable to tolerate **TWO** biologic DMARDs (see Appendix) for at least 12 weeks; AND
7. Member has had a negative tuberculosis test within the past 12 months.
8. **Dosage allowed/Quantity limit:** 400 mg subcutaneously (two injections of 200 mg) once a week at weeks 0, 2, and 4, followed by 200 mg subcutaneously every other week or 400 mg subcutaneously every four weeks.

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:
1. Chart notes have been provided showing improvement of signs and symptoms of disease such as decreased morning stiffness, tenderness or inflammatory back pain, improved quality of life, etc.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Crohn's Disease (CD)

For **initial** authorization:
1. Member is 18 years of age or older with moderately to severely active CD; AND
2. Medication must be prescribed by or in consultation with a gastroenterologist; AND
3. Member has had a documented trial and inadequate response, or intolerance to **ONE** of the following conventional therapies:
   a) Corticosteroid;
   b) 6-mercaptopurine, azathioprine, or methotrexate; OR
4. Provider attests member has severe disease that requires immediate use of an advanced therapy (biologic, JAK inhibitor, etc.) agent such as penetrating or fistulizing disease, multiple resections, etc.; AND
5. Member has tried and failed, or unable to tolerate **TWO** biologic DMARDs (see Appendix) for at least 12 weeks; AND
6. Member has had a negative tuberculosis test within the past 12 months.
7. **Dosage allowed/Quantity limit:** 400 mg subcutaneously (two injections of 200 mg) once a week at weeks 0, 2, and 4, followed by 400 mg subcutaneously every four weeks.

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:
1. Chart notes have been provided showing improvement in signs and symptoms of CD such as mucosal healing, fewer flare-ups of symptoms, improved quality of life, etc..

If all the above requirements are met, the medication will be approved for an additional 12 months.

Plaque Psoriasis (PsO)

For **initial** authorization:
1. Member must be 18 years of age or older; AND
2. Medication must be prescribed by or in consultation with a dermatologist; AND
3. Member has clinical documentation of moderate to severe plaque psoriasis characterized by 3% or more of body surface area (BSA) or disease affecting sensitive areas (e.g., hands, feet, face, genitals, etc.); AND
4. Member has tried and failed to respond to treatment with **ONE** of the following:
   a) At least 12 weeks of photochemotherapy (i.e., psoralen plus ultraviolet A therapy);
   b) At least 12 weeks of phototherapy (i.e., UVB light therapy, Excimer laser treatments);
   c) At least a 4-week trial with topical antipsoriatic agents (i.e., anthralin, calcipotriene, coal tar, corticosteroids, tazarotene, tacrolimus, pimecrolimus);
   d) At least a 12-week trial of a systemic conventional DMARD (i.e., cyclosporine, methotrexate, acitretin; AND
5. Member has tried and failed, or unable to tolerate **TWO** biologic DMARDs (see Appendix) for at least 12 weeks; AND
   a)
6. Member has had a negative tuberculosis test within the past 12 months.
7. **Dosage allowed/Quantity limit:** 400 mg subcutaneously (two injections of 200 mg) every other week. For members with weight 90 kg or less, may consider 400 mg subcutaneously (two injections of 200 mg) once a week at weeks 0, 2, and 4, followed by 200 mg subcutaneously every other week.

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:
1. Chart notes have been provided showing improvement of signs and symptoms of disease such as documented member's BSA improvement, etc.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Psoriatic Arthritis (PsA)

For **initial** authorization:
1. Member must be 18 years of age or older; AND
2. Medication must be prescribed by or in consultation with a rheumatologist or a dermatologist; AND
3. Member has a documented diagnosis of active PsA; AND
4. Member has met a 4-week trial of an NSAID taken at maximally tolerated doses **AND** a 3-month trial of a conventional DMARD agent (e.g., methotrexate, sulfasalazine, cyclosporine, etc.) unless **ONE** of the following situations is met:
   a) Conventional DMARD is **NOT** required for:
      i) Concomitant axial disease (i.e., involving sacroiliac joint and spine) or enthesitis; OR
   b) NSAID and conventional DMARD are **NOT** required for:
      i) Severe PsA (defined as having at least one of the following: erosive disease, active PsA at many sites including dactylitis or enthesitis, elevated levels of ESR or CRP, joint deformities, or major impairment in quality of life); AND
5. Member has tried and failed, or unable to tolerate **TWO** biologic DMARDs (see Appendix) for at least 12 weeks; AND
6. Member has had a negative tuberculosis test within the past 12 months.
7. **Dosage allowed/Quantity limit:** 400 mg subcutaneously (two injections of 200 mg) once a week at weeks 0, 2, and 4, followed by 200 mg subcutaneously every other week or 400 mg subcutaneously every 4 weeks.

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:
1. Chart notes have been provided showing improvement of signs and symptoms of disease such as decreased joint swelling and pain, improved skin appearance, improved quality of life, etc.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Rheumatoid Arthritis (RA)

For **initial** authorization:
1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a rheumatologist; AND
3. Member has a documented diagnosis of moderately to severely active RA; AND
4. Member must have a trial and failure of, or intolerance to methotrexate for at least 3 months; *Note*: If methotrexate is contraindicated, one of the following conventional DMARDs must be trialed instead: leflunomide, sulfasalazine, or hydroxychloroquine; AND
9. Member has tried and failed, or unable to tolerate **TWO** biologic DMARDs (see Appendix) for at least 12 weeks; AND
5. Member has had a negative tuberculosis test within the past 12 months.
6. **Dosage allowed/Quantity limit:** 400 mg subcutaneously (two injections of 200 mg) once a week at weeks 0, 2, and 4, followed by 200 mg subcutaneously every other week or 400 mg subcutaneously every 4 weeks.

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:
1. Chart notes demonstrate improvement of RA signs and symptoms such as fewer number of painful and swollen joints, achievement of remission, slowed progression of joint damage, etc.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Polyarticular Juvenile Idiopathic Arthritis (pJIA)

For **initial** authorization:
1. Member is at least 2 years of age; AND
2. Medication is prescribed by or in consultation with a rheumatologist; AND
3. Member has a documented diagnosis of active pJIA; AND
4. Member has had an 8-week trial and failure of a conventional DMARD (e.g., methotrexate, leflunomide); AND
5. Member has tried and failed, or unable to tolerate **TWO** biologic DMARDs (see Appendix) for at least 12 weeks; AND
6. Member has had a negative tuberculosis test within the past 12 months.
7. **Dosage allowed/Quantity limit:**

Weight	Loading dose	Maintenance dose (starting at week 6)
10 kg to < 20 kg	100 mg at week 0, 2, 4	50 mg every 2 weeks
20 kg to < 40 kg	200 mg at week 0, 2, 4	100 mg every 2 weeks
40 kg or greater	400 mg at week 0, 2, 4	200 mg every 2 weeks

Doses less than 200 mg require administration by a health care professional using the vial kit.

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes have been provided showing improvement of signs and symptoms of disease such as decreased joint swelling, decreased pain, and improved quality of life, etc.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Cimzia (certolizumab pegol) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
05/08/2017	New policy for Cimzia created. Policies SRx-0041 and SRx-0042 achieved. New diagnosis of AS with criteria was added. For diagnosis of CD: TNF inhibitor Humira and corticosteroids trials were added. For PsA: TNF inhibitors Humira and Enbrel were listed as required trials. For RA: non-biologic DMARDS were listed, and TNF inhibitors Humira and Enbrel were listed as required trials. List of diagnoses considered not medically necessary was added.
08/15/2018	Exception to pregnant member or those who are planning on becoming pregnant or are currently breastfeeding was added to each diagnosis in TNF requirement criterion. New indication of Plaque Psoriasis added. A requirement to have documented radiographic change involving the sacroiliac joints for diagnosis of AS was removed, and criteria of increased occiput to wall distance and post rest stiffness were added.

	Drug trials length were clarified as 4 weeks in length with each NSAID and 12 weeks in length with each Enbrel and Humira.
02/26/2019	Status changed to preferred. Humira and Enbrel trials removed from criteria; references edited. Initial authorization length increased to 12 months for PsO. TB test allowed to be done within 12 months prior to initiation of therapy; chest x-ray option removed. Symptoms of back pain for AS extended till before age of 50. Other drugs options allowed for PsA if there is an intolerance or contraindication to methotrexate. "Immunosuppressant therapies" changed to "treatment of traditional first-line oral/systemic" therapies. Reauthorization criteria on documented member's PASI score improvement incorporated into general chart noted documentation requirements.
11/22/2020	Replaced list of excluded diagnoses with the generic statement. Updated references. For all diagnoses: Removed repeat TB in reauth for all diagnoses. Updated quantity limit to 400 mg per 28 days (after loading doses). AS/nr-axSpA: Specified that diagnosis can be AS or nr-axSpA. Simplified list of spondyloarthritis symptoms/signs. Removed peripheral arthritis requirement – not relevant for this diagnosis. CD: Specified length of trials for conventional therapies. For severe disease, removed esophageal/gastroduodenal disease, specified that history of colonic resection must also be high risk for recurrence. PsO: Removed rheumatologist from prescriber. Changed BSA to 3% or sensitive area involvement. Removed PASI score requirement. PsA: Added requirement of diagnosis of PsA. Changed the trial section to be 4 weeks of an NSAID AND 3 months of a DMARD unless other circumstances apply (e.g., concomitant axial disease, severe PsA, etc.). RA: Changed the trials to require methotrexate as one of the non-biologic DMARD trials; only one trial is needed if member has poor prognostic factors.
1/18/2022	Transferred to new template. RA: Added new reference. Edited the terminology "non-biologic" DMARD to "conventional" DMARD. Changed from requiring 2 csDMARD to just 1. PsA: Clarified reauthorization criteria. Simplified wording for TB requirement. AS/nr-axSpA: Clarified reauthorization criteria. Simplified wording for TB requirement.
3/31/2023	Added 12-week trial of preferred TNF inhibitor to all diagnoses.
08/20/2024	AS/nr-axSpA: changed trial of each NSAID from 4 weeks to 2 weeks for a total of 4 weeks of treatment per EULAR 22 guidelines; removed criteria requiring back pain for 3 or more months before the age of 50; removed positive HLA-B27 test from signs/symptoms of spondyloarthritis and changed to signs/symptoms inflammation; added axSpA to diagnosis list
09/26/2024	Removed trial and failure of a preferred TNF inhibitor from all indications. PsO: converted double trial of topicals + systemic therapy to a single trial with both topical and systemic options
02/13/2025	Updated references. Created criteria for new pJIA indication approval.
08/21/2025	Updated references. CD: removing duration from drug trials, replaced "biologics" with "advanced therapies (biologic, JAK inhibitor, etc.)", added provider attestation to severe disease that requires immediate use of advanced therapy and replaced requirements with examples of severe disease PsA and PsO: replaced "non-biologic" with "conventional"

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Appendix: Preferred Biologic Products

- Actemra, Tyenne
- Enbrel
- Preferred adalimumab product - adalimumab-ryvk, adalimumab-adaz, adalimumab-adbm, Hadlima, or Simlandi
- Rinvoq
- Cosentyx
- Otezla
- Skyrizi
- Yesintek, Steqeyma, ustekinumab-ttwe
- Tremfya

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