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HEALTHCARE COOPERATIVE

PHARMACY POLICY STATEMENT
Common Ground Healthcare Cooperative (CGHC)

DRUG NAME	**Cimzia (certolizumab pegol)**
BILLING CODE	Medical: J0717 Must use valid NDC for self-administered product
BENEFIT TYPE	Medical or Pharmacy
SITE OF SERVICE ALLOWED	Home/Office/Outpatient
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 five additional indications: Rheumatoid Arthritis, Psoriatic Arthritis, Plaque Psoriasis, Ankylosing Spondylitis and Non-Radiographic Axial Spondyloarthritis.

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

Ankylosing Spondylitis (AS)

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 ankylosing spondylitis (AS; AND
3. Medication must be prescribed by or in consultation with a rheumatologist; AND
4. Member has had a negative tuberculosis test within the past 12 months; AND
5. Member has had back pain for 3 months or more that began before the age of 50; AND
6. Member shows at least one of the following signs or symptoms of Spondyloarthritis:
   a) Elevated serum C-reactive protein (CRP) or erythrocyte sedimentation rate (ESR);
   b) Positive HLA-B27 test;
   c) Sacroiliitis; AND
7. Member has tried and failed to respond to treatment with at least **two** NSAIDs taken at the maximum recommended dosages. Treatment failure requires at least 4 weeks of therapy with each NSAID without an adequate response.
8. Member has had a documented trial and inadequate response, or intolerance to two preferred biologic DMARDs (see Appendix.)
9. **Dosage allowed/Quantity limit:** 400 mg (two injections of 200 mg) once a week at weeks 0, 2, and 4, followed by 200 mg every other week or 400 mg every four weeks.

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

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For **reauthorization**:
1. Chart notes have been provided showing improvement of signs and symptoms of disease (ie. 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.

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:
10. Member must be 18 years of age or older; AND
11. Member has a documented diagnosis of active non-radiographic axial spondyloarthritis (nr-axSpA); AND
12. Medication must be prescribed by or in consultation with a rheumatologist; AND
13. Member has had a negative tuberculosis test within the past 12 months; AND
14. Member has had back pain for 3 months or more that began before the age of 50; AND
15. Member shows at least one of the following signs or symptoms of Spondyloarthritis:
    a) Elevated serum C-reactive protein (CRP) or erythrocyte sedimentation rate (ESR);
    b) Positive HLA-B27 test;
    c) Sacroiliitis; AND
16. Member has tried and failed to respond to treatment with at least **two** NSAIDs taken at the maximum recommended dosages. Treatment failure requires at least 4 weeks of therapy with each NSAID without an adequate response.
17. **Dosage allowed/Quantity limit:** 400 mg (two injections of 200 mg) once a week at weeks 0, 2, and 4, followed by 200 mg every other week or 400 mg every four weeks.

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

For **reauthorization**:
2. Chart notes have been provided showing improvement of signs and symptoms of disease (ie. 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 negative tuberculosis test within the past 12 months; AND
4. Member has had a documented trial and inadequate response, or intolerance to at least **one** of the following conventional therapies: a 4-week trial of a corticosteroid OR a 12-week trial of 6-mercaptopurine, azathioprine, or methotrexate; OR
5. Member has severe disease that requires immediate use of a biologic agent, as indicated by **one** of the following:
    a) Extensive small bowel disease involving more than 100 cm;
    b) History of bowel or colon resection and is at high risk for CD recurrence (e.g., smoker, <30 years old, 2 or more resections, penetrating/fistulizing disease, etc.);

c) Fistulizing disease; AND
6. Member has had a documented trial and inadequate response, or intolerance to two preferred biologic DMARDs (see Appendix.)
7. **Dosage allowed/Quantity limit:** 400 mg (two injections of 200 mg) once a week at weeks 0, 2, and 4, followed by 400 mg 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 (defined 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 had a negative tuberculosis test within the past 12 months; AND
5. Member has tried and failed to respond to treatment with at least **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); AND
6. Member has tried and failed, or unable to tolerate a systemic non-biologic DMARD (i.e., cyclosporine, methotrexate, acitretin) for at least 12 weeks; AND
7. Member has tried and failed, or unable to tolerate two biologic DMARDs (see Appendix) for at least 12 weeks.
8. **Dosage allowed/Quantity limit:** 400 mg (two injections of 200 mg) every other week. For members with weight 90 kg or less, may consider 400 mg (two injections of 200 mg) once a week at weeks 0, 2, and 4, followed by 200 mg 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 (e.g., 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 psoriatic arthritis (PsA); AND

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4. Member has had a negative tuberculosis test within the past 12 months; AND
5. Member has met a 4-week trial of an NSAID taken at maximally tolerated doses AND a 3-month trial of a non-biologic DMARD agent (e.g., methotrexate, sulfasalazine, cyclosporine, etc.) unless **one** of the following situations is met:
   a) Non-biologic DMARD is not required for:
      i) Concomitant axial disease (i.e., involving sacroiliac joint and spine) or enthesitis; OR
   b) NSAID and non-biologic 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
6. Member has tried and failed, or unable to tolerate two biologic DMARDs (see Appendix) for at least 12 weeks.
7. **Dosage allowed/Quantity limit:** 400 mg (two injections of 200 mg) once a week at weeks 0, 2, and 4, followed by 200 mg every other week or 400 mg 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 (ie. 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
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 (two injections of 200 mg) once a week at weeks 0, 2, and 4, followed by 200 mg every other week or 400 mg 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 (e.g. 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.

Common Ground Healthcare Cooperative (CGHC) 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.

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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.
2/10/2023	Added Amjevita to Appendix as preferred alternative

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Appendix Preferred Biologic Products	
Approved for Rheumatoid Arthritis	• Actemra *(requires step through preferred adalimumab product: Humira, Hadlima, Adalimumab-adaz, Adalimumab-fkjp)* • Enbrel • Humira • Hadlima • Adalimumab-adaz • Adalimumab-fkjp
Approved for Juvenile Idiopathic Arthritis	• Actemra *(requires step through preferred adalimumab product: Humira, Hadlima, Adalimumab-adaz, Adalimumab-fkjp)* • Enbrel • Humira • Hadlima • Adalimumab-adaz • Adalimumab-fkjp
Approved for Ankylosing Spondylitis	• Cosentyx • Enbrel • Humira • Hadlima • Adalimumab-adaz • Adalimumab-fkjp • Rinvoq
Approved for Non-radiographic Axial	• Cimzia • Cosentyx
Approved for Atopic Dermatitis	• Rinvoq
Approved for Psoriatic Arthritis	• Cosentyx • Enbrel • Humira • Hadlima • Adalimumab-adaz • Adalimumab-fkjp • Otezla • Skyrizi • Stelara • Tremfya
Approved for Psoriasis	• Cosentyx • Enbrel • Humira • Hadlima

	• Adalimumab-adaz • Adalimumab-fkjp • Otezla • Skyrizi • Stelara • Tremfya
Approved for Crohn's Disease	• Humira • Hadlima • Adalimumab-adaz • Adalimumab-fkjp • Stelara
Approved for Ulcerative Colitis	• Humira • Hadlima • Adalimumab-adaz • Adalimumab-fkjp • Stelara • Rinvoq