CareSource

PHARMACY POLICY STATEMENT **Indiana Medicaid**	
DRUG NAME	Cimzia (certolizumab pegol)
BILLING CODE	For medical – J0717 (1 unit = 1 mg) Must use valid NDC code for self-administered product
BENEFIT TYPE	Pharmacy or Medical
SITE OF SERVICE ALLOWED	Outpatient/Office/Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Preferred Product) QUANTITY LIMIT— 400 mg per 28 days (after loading doses)
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Cimzia (certolizumab pegol) is a **preferred** product and will only be considered for coverage under the **pharmacy or medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

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 ankylosing spondylitis (AS) or active non-radiographic axial spondyloarthritis (nr-axSpA); AND
3. Medication must be prescribed by or in consultation with a rheumatologist; AND
4. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), interferon-gamma release assay (IGRA)) within 12 months prior to starting therapy; 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. **Dosage allowed:** 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 member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:
1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided showing improvement of signs and symptoms of disease.

If member meets all the reauthorization requirements above, 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. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), interferon-gamma release assay (IGRA)) within 12 months prior to starting therapy; 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.
6. **Dosage allowed:** 400 mg (two injections of 200 mg) once a week at weeks 0, 2, and 4, followed by 400 mg every four weeks.

If member meets all the requirements listed above, 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 member meets all the reauthorization requirements above, 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. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), interferon-gamma release assay (IGRA)) within 12 months prior to starting therapy; 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 treatment with at least **two** of the following: Cimzia, Cosentyx, Enbrel, Otezla and Siliq. Treatment failure requires at least 12 weeks of therapy with each drug.
8. **Dosage allowed:** 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 member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:
1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided showing improvement of signs and symptoms of disease (e.g., documented member's BSA improvement, etc.).

If member meets all the reauthorization requirements above, 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
4. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), interferon-gamma release assay (IGRA)) within 12 months prior to starting therapy; 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).
6. **Dosage allowed:** 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 member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:
1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided showing improvement of signs and symptoms of disease.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

RHEUMATOID ARTHRITIS (RA)

For **initial** authorization:
1. Member must be 18 years of age or older with moderately to severely active RA; AND
2. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), interferon-gamma release assay (IGRA)) within 12 months prior to starting therapy; AND
3. Medication must be prescribed by or in consultation with a rheumatologist; AND

4. Member must have a trial and failure of, or intolerance to methotrexate and **one** other non-biologic DMARD (i.e., hydroxychloroquine, sulfasalazine, and leflunomide) for 3 months per trial, either together or separately.
   Note: only one non-biologic DMARD is required if member has a poor prognostic factor such as high swollen joint count, presence of early joint erosions, presence of autoantibodies (RF and/or ACPA).
5. **Dosage allowed:** 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 member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:
1. Member must be in compliance with all other initial criteria; AND
2. 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 member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Cimzia (certolizumab pegol) not medically necessary for the treatment of the diseases that are not listed in this document

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.

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Effective date: 04/01/2021
Revised date: 11/22/2020