I. Medication Description

Cimzia is a unique anti-TNF biologic that contains a Fab fragment of a humanized antibody that is a potent neutralizer of TNF-alpha. It is chemically attached to polyethylene glycol (PEG, pegylated) and is administered subcutaneously every 2—4 weeks. Unlike Enbrel, Remicade, and Humira, Cimzia does not contain an Fc region and thus, does not fix complement or cause antibody-dependent cell-mediated cytotoxicity.

II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for every request.

III. Policy

Medical Benefit: See Sections A and C
Formulary 1: See Sections A and B
Formulary 2: See Sections A and B
Formulary 3/Exclusive: See Sections A and B
Formulary 4/AON: See Sections A and B

A. Coverage of Cimzia is provided for the following conditions when the listed criteria are met:

- Ankylosing spondylitis (active disease):
  - Prescribed by a rheumatologist AND
  - Member has had inadequate results with at least two NSAIDs (unless NSAIDs are contraindicated)

- Non-radiographic axial spondyloarthritis (active disease):
  - Prescribed by a rheumatologist AND
  - Member has objective signs of inflammation AND
  - Member has had inadequate results with at least two NSAIDs (unless NSAIDs are contraindicated)

- Crohn’s disease (moderate to severe):
  - Prescribed by a gastroenterologist AND
  - At least ONE of the following criteria is met:
    - Member has had an inadequate response to or not tolerated immune modulators (e.g. azathioprine, 6-MP, methotrexate) OR
    - Member has not responded to steroids or is steroid refractory OR
The member has fistulizing disease

- **Plaque psoriasis (moderate to severe):**
  - Prescribed by a dermatologist or a rheumatologist **AND**
  - At least 10% of BSA affected or less than 10% BSA affected but with palmar, plantar, head/neck, or genitalia involvement **AND**
  - Member has had an inadequate response to PUVA or UVB therapy unless contraindicated **AND**
  - Member has had an inadequate response to non-biologic systemic therapy (i.e. methotrexate, cyclosporine, acitretin) unless contraindicated

- **Psoriatic arthritis (active disease):**
  - Prescribed by a rheumatologist or dermatologist **AND**
  - If predominantly axial disease is documented, the member has experienced treatment failure with at least two oral NSAIDs (unless NSAIDs are contraindicated)

- **Rheumatoid arthritis (moderate to severe disease):**
  - Prescribed by a rheumatologist **AND**
  - Member has tried therapy with at least one non-biologic DMARD with either treatment failure after 12 weeks or intolerable side effects (unless DMARDs are contraindicated)

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**B. Pharmacy benefit coverage of Cimzia is provided when the following step criteria have been met:**

- When requesting coverage of a brand medication for which a plan-preferred A/B rated generic is available, there is sufficient evidence that the use of the A/B rated generic equivalent has resulted in inadequate results **AND**
- For ankylosing spondylitis, the member has tried therapy with at least TWO of the following plan-preferred medications: Cosentyx, Enbrel, or Humira **OR**
- For Crohn’s disease, the member has tried therapy with the plan-preferred medication (Humira) **OR**
- For psoriatic arthritis, the member has tried therapy with at least TWO of the following plan-preferred medications: Cosentyx, Enbrel, Humira, Stelara SC or Xeljanz/Xeljanz XR **OR**
- For plaque psoriasis, the member has tried therapy with at least TWO of the following plan-preferred medications: Cosentyx, Humira, Otezla, Skyrizi, Stelara SC or Tremfya **OR**
- For rheumatoid arthritis, the member has tried therapy with at least TWO of the following plan-preferred medications: Actemra SC, Enbrel, Humira, Rinvoq or Xeljanz/XR **OR**
- When at least ONE of the following criteria have been met (plan-preferred medications are diagnosis-specific):
  - The plan-preferred medications are contraindicated or will likely cause an adverse reaction by or physical or mental harm to the member.
  - The plan-preferred medications are expected to be ineffective based on the known clinical history and conditions of the member and the member’s prescription drug regimen.
  - The member has tried the plan-preferred medications or another prescription drug in the same pharmacologic class or with the same mechanism of action and such prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event.
  - The member is stable on the medication selected by their healthcare professional for the medical condition under consideration (where “stable” is defined as receiving the medication for an adequate period of time, have achieved optimal response, and continued favorable outcomes are expected UNLESS the medication was initially selected solely due to the availability of a drug sample or a coupon card and the member does not otherwise meet the definition of “stable”).
The plan-preferred medication is not in the best interest of the member because it will likely cause a significant barrier to the member’s adherence or to compliance with the member’s plan of care, will likely worsen a comorbid condition of the member, or will likely decrease the member’s ability to achieve or maintain reasonable functional ability in performing daily activities.

C. Medical benefit coverage of Cimzia is provided when the following step criteria have been met:
   • When requesting coverage of a brand medication for which a plan-preferred A/B rated generic is available, there is sufficient evidence that the use of the A/B rated generic equivalent has resulted in inadequate results AND
   • When the member has tried therapy with one diagnosis-appropriate plan-preferred medication (Simponi Aria, Remicade, or Stelara) OR when at least ONE of the following criteria have been met:
      o The plan-preferred medications are contraindicated or will likely cause an adverse reaction by or physical or mental harm to the member.
      o The plan-preferred medications are expected to be ineffective based on the known clinical history and conditions of the member and the member’s prescription drug regimen.
      o The member has tried the plan-preferred medications or another prescription drug in the same pharmacologic class or with the same mechanism of action and such prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event.
      o The member is stable on the medication selected by their healthcare professional for the medical condition under consideration (where “stable” is defined as receiving the medication for an adequate period of time, have achieved optimal response, and continued favorable outcomes are expected UNLESS the medication was initially selected solely due to the availability of a drug sample or a coupon card and the member does not otherwise meet the definition of “stable”).
      o The plan-preferred medication is not in the best interest of the member because it will likely cause a significant barrier to the member’s adherence or to compliance with the member’s plan of care, will likely worsen a comorbid condition of the member, or will likely decrease the member’s ability to achieve or maintain reasonable functional ability in performing daily activities.

IV. Quantity Limitations

• For the treatment of plaque psoriasis:
   o Up to 800 mg per 28 days OR
   o For some members with body weight ≤ 90 kg:
     ▪ First 4 weeks (induction dosing): up to 1200 mg
     ▪ Week 5 and after: 400 mg per 28 days

• For all other indications:
   o First 4 weeks (induction dosing): 1200mg
   o Week 5 and after: 400mg per 28 days

V. Coverage Duration

Coverage is provided for 12 months and may be renewed.

VI. Coverage Renewal Criteria
Coverage may be renewed in 12 month intervals in situations where the member has responded favorably to therapy and in the absence of unacceptable toxicity from the drug.

VII. Billing/Coding Information

- J0717: 1mg of Cimzia® = 1 billable unit
- Available as: Cimzia® 400mg Kit, 200mg/ml prefilled syringe, 200mg/ml Starter Kit
- Pertinent indications:
  - Rheumatoid Arthritis: M05.00, M05.30, M05.60, M06.1, M06.9
  - Crohn’s Disease: K50.00, K50.10, K50.80, K50.90
  - Psoriatic Arthritis: L40.54, L40.59
  - Ankylosing Spondylitis: M45.9
  - Plaque Psoriasis: L40

VIII. Summary of Policy Changes

- 4/1/11: Prescriptions required by pertinent specialist for diagnosis
- 6/1/11:
  - Clarified that coverage under the pharmacy benefit for RA requires failed trials with both plan-preferred medications (Enbrel® and Humira®) first
  - Specific criteria for specialists, concurrent/past medication trials, etc. outlined for each diagnosis
  - Renewal period lengthened to standard 12 months
  - Differences between criteria for medical and pharmacy benefit specified/reworded
- 8/11:
  - Trial of Humira required prior to self-administered Cimzia for the treatment of CD
  - Coverage under medical benefit extended to allow for up to 12 month intervals
- 12/15/12: no changes
- 7/1/13: Medical, Commercial Rx, and Medicaid/FHP Rx criteria differentiated
- 10/15/13: criteria for psoriatic arthritis indication added
- 1/1/14: J code updated
- 3/15/14: criteria for ankylosing spondylitis added
- 1/1/15:
  - Initial approval duration for CD diagnosis increased to 12 months
  - Quantity limits changed to total mg per month allowed
- 7/1/15: formulary distinctions made
- 9/15/15: ICD9-ICD10 codes added
- 10/1/15: ICD9 codes removed
- 7/19/16: no policy changes
- 1/1/17: step therapy rules updated on the pharmacy benefit and medical benefit
- 5/1/17: step therapy criteria added
- 6/21/17: no policy changes
- 1/1/18: step criteria updated
IX. References

*These guidelines are not applicable to benefits covered under Medicare Advantage. Medicare Advantage benefit coverage requests are reviewed in accordance with the guidance set forth in Chapter 15 Section 50 of the Centers for Medicare & Medicaid Services Medicare Benefit Policy Manual.

The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.

The preceding policy applies only to members for whom the above named pharmacy benefit medications are included on their covered formulary. Members with closed formulary benefits are subject to trying all appropriate formulary alternatives before a coverage exception for a non-formulary medication will be considered.

The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.