CIMZIA® (certolizumab pegol)

LENGTH OF INITIAL AUTHORIZATION: UP TO ONE YEAR

REVIEW CRITERIA:

**Rheumatoid Arthritis**

- Patient is ≥ 18 years of age
- Patient has a documented diagnosis of moderate to severe rheumatoid arthritis
- A negative tuberculin test (TB) prior to initiating therapy and results have been provided
- Patient has had an inadequate response, intolerance, or contraindication (clinical documentation must be submitted demonstrating response to previous therapies) to one or more non-biologic DMARDs (i.e. methotrexate, leflunomide, sulfasalazine, hydroxychloroquine) for at least 3 consecutive months AND
- Patient has had a trial of at least one of the preferred alternatives and experienced inadequate response or intolerance. If a preferred agent(s) is contraindicated, trial of an alternative preferred agent is required, if appropriate.

**Ankylosing Spondylitis:**

- Patient is ≥ 18 years of age
- Patient has a documented diagnosis of ankylosing spondylitis
- A negative tuberculin test (TB) prior to initiating therapy and results have been provided
- Patient has had an inadequate response, intolerance, or contraindication (clinical documentation must be submitted demonstrating response previous therapies) with the following:
  - One or more non-steroidal anti-inflammatory drugs – NSAIDs (trial at maximum dose for at least 2-3 weeks before considering them as failures) OR
  - Analgesic agents (acetaminophen or codeine) if NSAIDs do not completely control the pain OR
  - Sulfasalazine (if peripheral joint involvement is present) AND
  - Patient has had a trial of at least one of the preferred alternatives and experienced inadequate response or intolerance. If a preferred agent(s) is contraindicated, trial of an alternative preferred agent is required, if appropriate.

**Crohn’s Disease**

- Patient is ≥ 18 years of age
- Patient has a documented diagnosis of moderate to severe Crohn’s disease
- A negative tuberculin test (TB) prior to initiating therapy and results have been provided
- Patient has inadequate responses, intolerance, or has contraindications to conventional therapy (clinical documentation must be submitted demonstrating response to previous therapies):
  - Budesonide, mesalamine, or corticosteroids (i.e. prednisone, methylprednisolone) OR
  - Non-biologic DMARDs (e.g. azathioprine, methotrexate, mercaptopurine) AND
  - Patient has an inadequate response, intolerance, or has contraindications to Humira®
Psoriatic Arthritis

- Patient is ≥ 18 years of age
- A negative tuberculin test (TB) prior to initiating therapy and results have been provided
- Patient has active psoriatic arthritis for at least 6 months defined as:
  - ≥ 3 swollen joints AND
  - ≥ 3 tender joints AND
- Patient has had an inadequate response, intolerance, or contraindication (clinical documentation must be submitted demonstrating response to previous therapies) with the following:
  - One or more non-steroidal anti-inflammatory drugs – NSAIDs (trial at maximum dose for at least 2-3 weeks before considering them as failures) AND
  - One or more non-biologic disease modifying anti-rheumatic drugs DMARDs (i.e. methotrexate, sulfasalazine, leflunomide, cyclosporine) AND
  - Patient has had a trial of at least one of the preferred alternatives and experienced inadequate response or intolerance. If a preferred agent(s) is contraindicated, trial of an alternative preferred agent is required, if appropriate.

Plaque Psoriasis

- Patient is ≥ 18 years of age.
- Patient has documented diagnosis of moderate to severe plaque psoriasis for at least 6 months with at least one of the following:
  - Incapacitation due to plaque location (e.g., head and neck, palms, soles, or genitalia); OR
  - Involvement of at least 10 percent of body surface area (BSA); OR
  - Psoriasis Area and Severity Index (PASI) score of 12 or greater; AND
- Patient is free of any clinically important active infections; AND
- Patient has a negative tuberculin test (TB) prior to initiating therapy and results have been provided; AND
- Patient did not respond adequately (or is not a candidate) to a 3-month minimum trial of at least 1 systemic agent (e.g., immunosuppressives, retinoic acid derivatives, and/or methotrexate); AND
- Patient did not respond adequately (or is not a candidate) to a 3 month minimum trial of phototherapy (e.g., Psoralens with UVA light (PUVA) OR UVB with coal tar or dithranol); AND
- Patient has had a trial of at least one of the preferred alternatives and experienced inadequate response or intolerance. If a preferred agent(s) is contraindicated, trial of an alternative preferred agent is required, if appropriate.

DOSING & ADMINISTRATION:

Rheumatoid Arthritis
400 mg administered by subcutaneous injection initially and at weeks 2 and 4, followed by 200 mg every other week; for maintenance dosing, 400 mg every 4 weeks can be considered

Ankylosing Spondylitis
400 mg (given as 2 subcutaneous injections of 200 mg each) initially and at weeks 2 and 4; followed by 200 mg every other week or 400 mg every 4 weeks.
**Crohn’s Disease**
400 mg administered by subcutaneous injection initially and at weeks 2 and 4; if response occurs, follow with 400 mg every four weeks

**Psoriatic Arthritis**
400 mg administered by subcutaneous injection initially and at weeks 2 and 4, followed by 200 mg every other week; for maintenance dosing, 400 mg every 4 weeks can be considered.

**Plaque Psoriasis**
400 mg subcutaneously every other week. For some patients (with body weight ≤ 90 kg), a dose of 400 mg subcutaneously initially, and at weeks 2 and 4, followed by 200 mg every other week may be considered.

**DOSAGE FORMS:**

**Cimzia Starter Kit**
Kit contains three (3) sets of two (2) prefilled glass syringes of one (1) mL each containing Cimzia 200mg/mL. The kit provides sufficient drug supply for the initial three (3) induction doses at the start of treatment. A total of six (6) prefilled glass syringes containing Cimzia 200 mg/mL solution

NOTE: Dispense quantity is 3 (three); max limit of one fill per 355 days

**Cimzia kit for Injection:**
Pack contains two (2) glass vials containing 200 mg each of lyophilized Cimzia for reconstitution

NOTE: Dispense quantity is 1 (one); max limit of one fill per 25 days

Prefilled Syringe:
Contains two (2) prefilled glass syringes of one (1) mL each containing Cimzia 200 mg/mL

NOTE: Dispense quantity is 1 (one); max limit of one fill per 25 days

**CONTINUATION OF THERAPY:**
- Documentation showing current patients are stable (have low disease activity or are in clinical remission) will be taken into consideration during the prior authorization review process regarding continuation of therapy with the same agent.