CIMZIA® (CERTOLIZUMAB PEGOL)

UTILIZATION MANAGEMENT CRITERIA

DRUG CLASS: Biologic Disease Modifying Anti-Rheumatic Drug (DMARD)

BRAND (generic) NAMES: Cimzia (certolizumab pegol injection)

- Supplied as a kit that includes 2 single-use prefilled syringes, each containing 200 mg (1 mL) of certolizumab pegol
- Supplied as a starter kit that includes 6 single-use prefilled syringes, each containing 200 mg (1 mL) of certolizumab pegol
- Also available as a kit that includes 2 vials each containing 200 mg of lyophilized certolizumab pegol for reconstitution

FDA-APPROVED INDICATIONS

Certolizumab pegol is a tumor necrosis factor (TNF) indicated for:

- Crohn’s Disease: Reducing signs and symptoms of Crohn’s disease and maintaining clinical response in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy.
- Rheumatoid Arthritis: Treatment of adults with moderately to severely active rheumatoid arthritis.
- Active psoriatic arthritis: Treatment of adult patients with active psoriatic arthritis.
- Ankylosing spondylitis: Treatment of adults with active ankylosing spondylitis.

COVERAGE AUTHORIZATION CRITERIA

Coverage is provided for Rheumatoid Arthritis if:

- Patient is an adult (≥ 18 years of age) with moderately to severely active rheumatoid arthritis, AND
- The patient has experienced a therapeutic failure or inadequate response to methotrexate; OR
- The patient is unable to receive methotrexate or has a contraindication to methotrexate; AND
- Patient has tried and failed, is intolerant to, or has a contraindication to TWO of the following: Enbrel, Humira, and Simponi.

Coverage is provided for Psoriatic Arthritis if:

- Patient is an adult (≥ 18 years of age) with active psoriatic arthritis, AND
- The patient has experienced a therapeutic failure or inadequate response to methotrexate; OR
- The patient is unable to receive methotrexate or has a contraindication to methotrexate; AND
• Patient has tried and failed, is intolerant to, or has a contraindication to TWO of the following: Enbrel, Humira, Simponi, and Stelara.

Coverage is provided for Crohn’s Disease if:
• Patient is an adult (≥ 18 years of age) with moderately to severely active Crohn’s disease, AND
• Patient has had an inadequate response to conventional therapy (e.g., corticosteroids, 5-aminosalicylates, azathioprine, 6-mercaptopurine, cyclosporine, metronidazole, methotrexate), AND
• Patient has tried and failed, is intolerant to, or has a contraindication to Humira.

Coverage is provided for Ankylosing Spondylitis if:
• Patient is an adult (≥ 18 years of age) with active ankylosing spondylitis, AND
• Patient has tried and failed, is intolerant to, or has a contraindication to TWO of the following: Enbrel, Humira, and Simponi.

Coverage is NOT provided if:
• Patient is using Cimzia in combination with other biologic agents (including, but not limited to, Enbrel, Humira, Stelara, Actemra, Remicade, Kineret, Xeljanz, Orencia, Entyvio, Simponi, Tysabri, or Rituxan).

QUANTITY LIMITATIONS
The allowed quantity for maintenance doses is two 200 mg injections every 28 days. This corresponds to maintenance doses of 400 mg every 28 days or 200 mg every other week.

WARNING: SERIOUS INFECTIONS AND MALIGNANCY
• Increased risk of serious infections leading to hospitalization or death including tuberculosis (TB), bacterial sepsis, invasive fungal infections (such as histoplasmosis), and infections due to other opportunistic pathogens.
• Cimzia should be discontinued if a patient develops a serious infection or sepsis.
• Perform test for latent TB; if positive, start treatment for TB prior to starting Cimzia.
• Monitor all patients for active TB during treatment, even if initial latent TB test is negative.
• Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers, of which Cimzia is a member. Cimzia is not indicated for use in pediatric patients.

DOSAGE AND ADMINISTRATION
Cimzia is administered by subcutaneous injection. The initial dose of Cimzia is 400 mg (given as two subcutaneous injections of 200 mg).
• For the treatment of Crohn’s Disease, 400 mg initially and at weeks 2 and 4. If response occurs, follow with 400 mg every four weeks.
• For the treatment of Rheumatoid Arthritis, 400 mg 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.
• For the treatment of **Psoriatic Arthritis**, 400 mg 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.

• For the treatment of **Ankylosing Spondylitis**, 400 mg initially and at weeks 2 and 4, followed by 200 mg every other week or 400 mg every 4 weeks.

**REFERENCES**