blue of california

certolizumab (CIMZIA)

Diagnoses Considered for Coverage:

- ankylosing spondylitis (AS)
- non-radiographic axial spondyloarthritis (nr-axSpA)
- Crohn's disease (CD)
- Psoriatic Arthritis (PsA)
- Rheumatoid Arthritis (RA)
- Plaque psoriasis (PsO)

1. **For ankylosing spondylitis (AS):**

- Prescribed by, or in consultation, with a rheumatologist, **and**
- Not being used in combination with other targeted immunotherapies (e.g., anti-TNFs, interleukin inhibitors, JAK inhibitors), **and**
- One of the following:
    - For patient with no bleeding or ulcer risk factors: Either inadequate response or non-GI related intolerable side effect with TWO prescription-strength oral NSAIDs, OR intolerable GI side effect with ONE prescription-strength oral NSAID monotherapy not relieved with addition of concomitant proton pump inhibitor (PPI) therapy
    - For patient with high-risk potential for development of GI bleed or ulcer: Inadequate response or intolerable side effect to ONE prescription-strength oral NSAID in combination with a proton pump inhibitor (PPI)
    - Patient unable to use NSAIDs due to history of GI bleed or ulcer, **and**
- Inadequate response or intolerable side effect with **TWO** preferred targeted immunotherapies (e.g. Cosentyx, Enbrel/Enbrel mini, Hadlima/Humira, Rinvoq, Xeljanz, Xeljanz XR), OR contraindication to ALL preferred agents, **and**
- Dose does not exceed FDA label maximum. **(**400 mg given at week #0, #2, and #4, then 400 mg every 4 weeks)

Coverage Duration: one year

2. **For non-radiographic axial spondyloarthritis (nr-axSpA):**

- Prescribed by, or in consultation, with a rheumatologist, **and**
- Not being used in combination with other targeted immunotherapies (e.g., anti-TNFs, interleukin inhibitors, JAK inhibitors), **and**
- One of the following:

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- For patient with no bleeding or ulcer risk factors: Either inadequate response or non-GI related intolerable side effect with TWO prescription-strength oral NSAIDs, OR intolerable GI side effect with ONE prescription-strength oral NSAID monotherapy not relieved with addition of concomitant proton pump inhibitor (PPI) therapy
- For patient with high-risk potential for development of GI bleed or ulcer: Inadequate response or intolerable side effect to ONE prescription-strength oral NSAID in combination with a proton pump inhibitor (PPI)
- Patient unable to use NSAIDs due to history of GI bleed or ulcer, **and**

- Dose does not exceed FDA label maximum. **(**400 mg given at week #0, #2, and #4, then 400 mg every 4 weeks)

Coverage Duration: one year

3. For diagnosis of moderate to severe Crohn's disease:

- Not being used in combination with other targeted immunomodulators (e.g., anti-TNFs, interleukin inhibitors, JAK inhibitors), and
- Dose does not exceed 400 mg given at week #0, #2, and #4, then 400 mg every 4 weeks, and
- Inadequate response or intolerable side effect or contraindication to Hadlima or Humira.

Coverage Duration: one year

4. For diagnosis of moderate to severe plaque psoriasis:

INITIAL AUTHORIZATION

- Prescribed by or in consultation with a dermatologist or rheumatologist, **and**
- Patient is at least 18 years old, **and**
- Inadequate response, intolerable side effect, or contraindication to one of the following: methotrexate, cyclosporine (Neoral), acitretin (Soriatane), PUVA/UVB, **and**
- Not being used in combination with another targeted immunomodulator*, **and**
- One of the following:
  - Baseline PASI score is 10 or more prior to initiating targeted immunotherapies (i.e. anti-TNFs, interleukin inhibitors, TYK2 inhibitors), **or**
  - Baseline BSA is 3% or more prior to initiating targeted immunotherapies (i.e. anti-TNFs, interleukin inhibitors), **or**

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- Sensitive area is involved (i.e. groin, face, etc.), **or**
- Disease is otherwise debilitating, **and**

- Inadequate response or intolerable side effect with **TWO** preferred agents [e.g., Cosentyx, Enbrel, Hadlima, Humira, Otezla Skyrizi, Stelara, Tremfya, OR contraindication to ALL preferred agents, and
- Dose does not exceed 400 mg SQ given every other week.

Coverage Duration: 48 weeks

REAUTHORIZATION

- Patient has shown improvement in the baseline PASI (or BSA if provided on initial request), **and**
- Not being used in combination with another targeted immunomodulator, **and**
- Dose does not exceed 400 mg SQ given every other week.

Coverage Duration: one year

5. **For non-radiographic axial spondyloarthritis (nr-axSpA):**

- Prescribed by, or in consultation, with a rheumatologist, **and**
- Not being used in combination with other targeted immunotherapies (e.g., anti-TNFs, interleukin inhibitors, JAK inhibitors), **and**
- One of the following:
    - For patient with no bleeding or ulcer risk factors: Either inadequate response or non-GI related intolerable side effect with TWO prescription-strength oral NSAIDs, OR intolerable GI side effect with ONE prescription-strength oral NSAID monotherapy not relieved with addition of concomitant proton pump inhibitor (PPI) therapy
    - For patient with high-risk potential for development of GI bleed or ulcer: Inadequate response or intolerable side effect to ONE prescription-strength oral NSAID in combination with a proton pump inhibitor (PPI)
    - Patient unable to use NSAIDs due to history of GI bleed or ulcer

  AND
- Dose does not exceed FDA approved maximum

Coverage Duration: one year

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6. For diagnosis of psoriatic arthritis:

- Prescribed by or in consultation with a rheumatologist, **and**
- Inadequate response or intolerable side effect with one DMARD agent OR patient has a medical reason why methotrexate, leflunomide, and sulfasalazine cannot be used, **and**
- Not being used in combination with other targeted immunotherapies (i.e. anti-TNFs, interleukin inhibitors, JAK inhibitors, Otezla), **and**
- Inadequate response or intolerable side effect with TWO preferred agents [e.g., Cosentyx, Enbrel, Hadlima/Humira, Otezla, Rinvoq, Stelara, Tremfya, Xeljanz/Xeljanz XR], OR contraindication to ALL preferred agents.
- Dose does not exceed 400 mg given at week #0, #2, and #4, then 200 mg every other week or 400 mg every 4 weeks.

Coverage Duration: one year

7. For diagnosis of rheumatoid arthritis:

1. Prescribed by or in consultation with a rheumatologist, **and**
2. Inadequate response, intolerable side effect, or contraindication to methotrexate, **and**
3. Not being used in combination with another targeted immunomodulator (i.e. anti-TNFs, IL-6 inhibitors, JAK inhibitors), **and**
4. Inadequate response or intolerable side effect with TWO preferred agents [e.g., Enbrel Enbrel Mini, Hadlima/Humira, Rinvoq, Xeljanz/Xeljanz XR, OR contraindication to ALL preferred agents, and
5. Dose does not exceed 400 mg given at week #0, #2, and #4, then 200 mg every other week or 400 mg every 4 weeks.

Coverage Duration: one year

Effective Date: 01/03/2024

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