

golimumab subcutaneous injection (SIMPONI)

Diagnoses Considered for Coverage:

- Ankylosing Spondylitis (AS)
- Psoriatic Arthritis (PsA)
- Rheumatoid Arthritis (RA)
- Ulcerative Colitis (UC)

Coverage Criteria:

For rheumatoid arthritis:

- Being prescribed by or in consultation with a rheumatologist, **and**
- Inadequate response, intolerable side effect, or contraindication to methotrexate, **and**
- Not being used in combination with another targeted immunomodulator, **and**
- Inadequate response or intolerable side effect with two BSC preferred agents (e.g. Enbrel/Enbrel mini, Hadlima, Humira, Rinvoq, and Xeljanz/Xeljanz XR) OR contraindication to ALL preferred agents, **and**
- Dose does not exceed 50 mg given SQ once a month

Coverage Duration: one year

For psoriatic arthritis:

- Being 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**
- Inadequate response or intolerable side effect with two BSC-preferred agents (e.g. Cosentyx, Enbrel, Hadlima, Humira, Otezla, Rinvoq, Skyrizi, Stelara, Tremfya, Xeljanz/Xeljanz XR) OR contraindication to ALL preferred agents, **and**
- Not being used in combination with other targeted immunotherapies, **and**
- Dose does not exceed 50 mg given SQ once a month

Coverage Duration: one year

For ankylosing spondylitis (AS):

- Being prescribed by or in consultation with a rheumatologist, **and**
- Inadequate response or intolerable side effect with two BSC preferred

- agents (e.g. Cosentyx, Enbrel/Enbrel mini, Hadlima/Humira, Rinvoq, Xeljanz, Xeljanz XR) OR contraindication to ALL preferred agents, **and**
- Not being used in combination with other targeted immunotherapies, **and**
 - Dose does not exceed 50 mg given SQ once every 4 weeks, **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, **or**
 - **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), **or**
 - Patient unable to use NSAIDs due to history of GI bleed or ulcer.

Coverage Duration: one year

For moderate to severe ulcerative colitis:

Initial Authorization:

- Inadequate response or intolerable side effect or contraindication to Humira or Hadlima, **and**
- Not being used in combination with other targeted immunotherapies, **and**
- Dose does not exceed 200 mg SQ given once on week #0, 100 mg SQ given once on week #2, followed by 100 mg SQ given thereafter every 4 weeks.

Coverage Duration: 6 weeks

Reauthorization

- Disease is stable and responding to Simponi therapy, **and**
- Dose does not exceed 100 mg given SQ once every 4 weeks.

Coverage Duration: one year

Effective: 01/03/2024