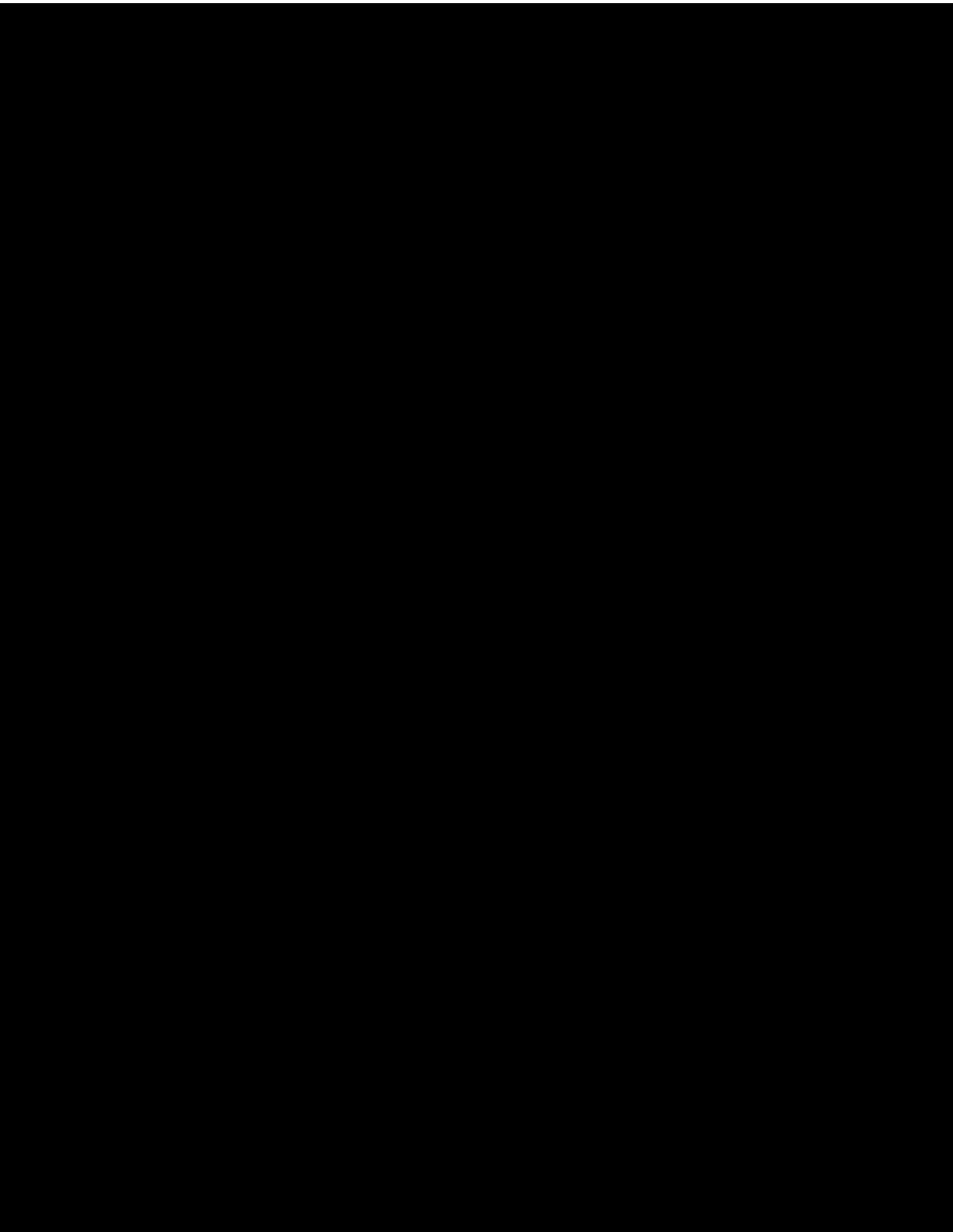


PHARMACY POLICY STATEMENT

Marketplace

| | |
|-------------------------|----------------------------|
| DRUG NAME | Simponi (golimumab) |
| BILLING CODE | Must use valid NDC |
| BENEFIT TYPE | Pharmacy |
| SITE OF SERVICE ALLOWED | Home |



Ulcerative Colitis (UC)

For **initial** authorization:

1. Member is 18 years of age or older with moderately to severely active UC; AND
2. Member has had a negative tuberculosis test within the past 12 months; AND
3. Medication must be prescribed by or in consultation with a gastroenterologist; AND
4. Member must have a documented trial and inadequate response with **one** of the following:
 - a) 3 months of 6-mercaptopurine or azathioprine;
 - b) 30 days of corticosteroid (e.g., budesonide, prednisone, methylprednisolone, etc.);
 - c) 3 months of 5-aminosalicylate (e.g., Asacol HD, Lialda, Pentasa, Delzicol, mesalamine, etc.);AND
5. Member has tried and failed at least two preferred biologic DMARDs for at least 3 months each, one of which must be another TNF inhibitor (same class as Simponi, see Appendix).
6. **Dosage allowed/Quantity limit:** 200 mg subcutaneously at week 0, followed by 100 mg at week 2, then 100 mg every 4 weeks thereafter.

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:

1. Chart notes have been provided showing improvement in signs and symptoms of UC (defined as clinical remission, decrease in rectal bleeding, decreased corticosteroid use, etc.).

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Simponi (golimumab) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE



Appendix: Preferred Biologic Products

Approved for Rheumatoid Arthritis

- Actemra
- Amjevita
- Avelumab
- Humira

Approved for Juvenile Idiopathic