Letter of Medical Necessity - SIMPONI® (golimumab)

[Insert physician letterhead]

[Insert Name of Medical Director]
[Insurance Company]
[Address]
[City, State, Zip]

RE: Patient Name
Policy Number
Claim Number

Dear [Insurance Company]:

I am writing to provide additional information to support my claim for the treatment of [insert patient name] with SIMPONI® (golimumab) for the treatment of **ulcerative colitis (UC).** SIMPONI® is an SQ option for adults with moderately to severely active UC who are corticosteroid dependent or have failed conventional therapy. In brief, treatment of [insert patient name] with SIMPONI® is medically appropriate, necessary, and should be a covered and reimbursed service.

Below, this letter outlines [insert patient name]'s relevant medical history, prognosis, treatment history, and treatment rationale.

Summary of Patient History

[Note: Exercise your medical judgment and discretion when providing a diagnosis and characterization of the patient's medical condition.]
* Patient's diagnosis, condition, and history
* Previous therapies the patient has undergone for the treatment of UC
* Patient's response to these therapies
* Brief description of the patient's recent symptoms and conditions
* Summary of your professional opinion of the patient's likely prognosis or disease progression without treatment with SIMPONI®

Rationale for Treatment

Given the patient's history, condition, and the published data supporting use of SIMPONI®, I believe the treatment of [insert patient name] with SIMPONI® is warranted, appropriate, and medically necessary for the following reasons: [Insert additional data support such as clinical response, clinical remissions, dosing from PURSUIT studies]

The attached [copies of clinical peer-reviewed published literature and package insert] provides the safety and efficacy of SIMPONI® in adult patients with moderately to severely active UC like [insert patient name].

SIMPONI® is indicated in adult patients with moderately to severely active ulcerative colitis who have demonstrated corticosteroid dependence or who have had an inadequate response to or failed to tolerate oral aminosalicylates, oral corticosteroids, azathioprine, or 6-mercaptopurine for:
• inducing and maintaining clinical response
• improving endoscopic appearance of the mucosa during induction
• inducing clinical remission
• achieving and sustaining clinical remission in induction responders

Dosage in Moderately to Severely Active Ulcerative Colitis
The recommended SIMPONI® induction dosage regimen is a 200 mg subcutaneous injection at Week 0, followed by 100 mg at Week 2, and then maintenance therapy with 100 mg every 4 weeks.

Please call my office at [insert telephone number] if I can provide you with any additional information. I look forward to receiving your timely response and approval of this claim.

Sincerely,

[Insert Doctor name and
participating provider number]

Enclosures

