

Sample Letter of Medical Necessity

[Physician Letterhead]

Attn: [Medical Director]
[Insurance Company]
[Address]
[City, State, ZIP code]

RE: [Patient Name]
[Date of Birth]
[Policy Number]
[Claim Number]

Letter of medical necessity for denial of VELSIPITY® (etrasimod): [Insert content and date]

Request: Authorization for treatment with VELSIPITY™ (etrasimod)

Diagnosis: [Diagnosis and ICD-10 code]

Dosage: 2 mg orally once daily

[Date]

Dear [Insert name],

I am writing on behalf of my patient, [Patient First and Last Name], to request that you approve coverage for VELSIPITY® (etrasimod) as a medically necessary treatment. VELSIPITY® is indicated for the treatment of adults with moderately to severely active ulcerative colitis (UC).¹ Your plan recently denied my request for VELSIPITY® for this patient due to [insert reason provided by plan and date]. This letter provides information about my patient's medical history, diagnosis, and current details regarding the medical necessity of treatment with VELSIPITY®.

Summary of Patient's Recent Clinical History

- Brief description of patient's current medical condition: symptomatic presentation, laboratory results, results of most recent endoscopic evaluation, if available
- Pharmaceutical UC treatment history: medications prescribed including conventional therapy, corticosteroids, and advanced therapies; response, lack or loss of response, tolerability issues, or discontinuation
- Additional patient factors deeming VELSIPITY® medically necessary, such as:
 - Rationale for oral route of administration
 - If the patient's disease state is consistent with isolated (ulcerative) proctitis, then consider including the rationale for prescribing a treatment with Phase 3, randomized clinical trial data for patients with isolated proctitis²
 - If the patient's clinical history is naïve to the use of biologic and/or JAK inhibitor, then consider including rationale for prescribing a treatment that has the safety and efficacy data in a subgroup of patients with no previous exposure to biologic and/or JAK inhibitor, which accounted for approximately 70% of the overall population¹
 - If applicable, patient's previous response to VELSIPITY® (eg, samples, participated in a voucher program)
- Summary of professional opinion of the patient's likely prognosis or disease progression without prescribed treatment
- Consider adding information about the safety and efficacy profile via the VELSIPITY® Package Insert at Section 6 (labeling.pfizer.com/ShowLabeling.aspx?id=19776#section-6) and Section 14 (labeling.pfizer.com/ShowLabeling.aspx?id=19776#section-12)¹

Given the patient's history, current clinical status, and completion of required baseline assessments, the patient is appropriate for VELSIPITY® as a medically necessary medication. [Please consult a gastroenterologist with experience managing ulcerative colitis in your review.] If you require any additional information or documentation, call my office at [phone number].

I look forward to your timely response.

Sincerely,

[Insert physician name and participating provider number]

References: **1.** Velsipity. Prescribing Information. New York; NY: Pfizer, Inc.; November 2023. **2.** Peyrin-Biroulet L, Dubinsky MC, Sands BE, et al. Efficacy and Safety of Etrasimod in Patients with Moderately to Severely Active Isolated Proctitis: Results from the Phase 3 ELEVATE UC Clinical Programme. *J Crohns Colitis*. 2024;jjae038. doi:10.1093/ecco-jcc/jjae038

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