**Guidance on Completing a Letter of Medical Necessity for ENTYVIO**

The following Letter of Medical Necessity is a template that you can modify by incorporating details related to your patient’s medical history, diagnosis, and treatment plan. Using this sample letter does not guarantee that insurance providers will provide reimbursement or coverage for ENTYVIO. Insurance providers may have specific forms or procedures for the authorization process that should be used instead of this

sample letter.

1. Download the Word doc template provided on pages 2-3.
2. Gather all the details regarding your patient’s medical diagnosis and history and attach any supporting documents.
3. Modify the Letter of Medical Necessity based on the medical history and clinical response of your patient. Fields for modification are bracketed in MAGENTA.
4. Submit the completed Letter of Medical Necessity with the prior authorization form to provide a more complete picture of your patient’s medical need for the insurance provider.

***Scroll down to page 2 for sample Letter of Medical Necessity.***

[Physician’s letterhead]

[Date] [Patient’s name]

[Health plan’s name] [Date of birth]

ATTN: [Department] [Case ID number]

[Medical director’s name] [Date(s) of service]

[Health plan’s address]

[City, State ZIP]

Letter of Medical Necessity for ENTYVIO® (vedolizumab)

Dear [Medical director’s name],

I am writing this letter on behalf of my patient, [patient’s name], to request coverage for ENTYVIO for the [intravenous/subcutaneous] treatment of moderately to severely active [Crohn’s disease (CD)/ulcerative colitis (UC)] ([insert appropriate ICD-10-CM code here]). I have read and acknowledged your drug coverage policy and [include a brief statement regarding your opinion on why ENTYVIO is an appropriate treatment for the patient]. This letter provides my clinical rationale along with relevant information about my patient’s medical history and treatment.

**Patient’s diagnosis and medical history**

[Patient’s name] is [a/an] [age]-year-old [male/female] who has been diagnosed with [CD/UC] as of [date of diagnosis]. [He/she] has been in my care since [date].

My rationale for prescribing ENTYVIO is based on [include a brief disease course of the patient, including the history of the disease, any symptoms, and previous treatments, such as completion of ENTYVIO IV doses if the patient with CD/UC is transitioning to the ENTYVIO Pen. Include a clinical assessment of the patient, response to treatment with ENTYVIO, side effects, and/or clinical response to other CD/UC treatments].

**Treatment plan**

In my clinical opinion, [patient’s name] should receive ENTYVIO for the following reasons:

[List your recommendations for why ENTYVIO is appropriate for this patient based on diagnosis and medical history. Include documentation of past treatments.]

|  |  |  |
| --- | --- | --- |
| History of previous therapies | Reason(s) for discontinuation of previous therapies | Duration of previous therapies |
|  |  |  |

I have reviewed your formulary for [CD/UC] and [summarize why the preferred drugs on formulary are not sufficient for your patient at this time].

**Summary**

I believe [insert reason for belief that treatment with ENTYVIO is appropriate]. I have attached relevant [lab test analyses/medical records/clinical studies] to support my decision. If you have any questions about this matter, please contact me at [physician’s phone number] or via email at [physician’s email]. Thank you for your time and consideration.

Sincerely,

[Physician’s signature]

**Enclosures**

[List and attach enclosures, which may include:

* Medical records
* Laboratory work
* ENTYVIO Prescribing Information
* Other supporting documentation]

US-VED-1977v3.0 08/24