Sample Letter of Medical Exception for ENTYVIO

[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]

Re: Letter of Medical Exception for ENTYVIO® (vedolizumab)

Dear [Medical/Pharmacy Director Name],

I am writing this letter of medical exception on behalf of [Patient Name], who is diagnosed with moderately to severely active [Crohn's disease (CD)/ulcerative colitis (UC)] ([primary and secondary ICD-10 codes]). I have read your coverage policy regarding my patient's diagnosis and am requesting coverage for [ENTYVIO intravenous (IV) infusion/ENTYVIO Pen for subcutaneous (SC) injection] since it is medically necessary for [Patient Name]. This letter provides my clinical rationale and relevant information you may need to consider the request.

I have been treating [Patient's Name], [a/an] [age]-year-old [male/female], since [Date] to manage their [CD/UC]. My rationale for prescribing [ENTYVIO IV/ENTYVIO Pen] is: [Include relevant medical information and why ENTYVIO is the most appropriate treatment option. If applicable, provide specific information regarding the treatments this patient has already received. If the patient has been receiving ENTYVIO IV and you are requesting the ENTYVIO Pen, list the number of prior IV infusions].

In my medical judgment, [include brief statement regarding opinion why ENTYVIO is an appropriate treatment for the patient]. I have attached the US Food and Drug Administration (FDA) approval letter for ENTYVIO, as well as [reference any supporting clinical data that would be relevant to support medical judgment].

If you have any further questions about this matter, please feel free to contact me at [physician phone number] or via email at [physician email]. Thank you for your time and consideration.

Sincerely,

[Physician's signature]

Physician sign-off

Enclosures: [List and attach additional documents, which may include Prescribing Information, clinical notes/medical records, US Food and Drug Administration approval letter, clinical studies and efficacy data, and/or clinical practice guidelines.]