

TEMPLATE LETTER OF MEDICAL EXCEPTION

This example letter is provided for guidance and reference only.

[Date]

[Payer Name]

[Payer Street Address]

[Payer City, State, and Zip Code]

Patient Name: [Patient Name]

Date of Birth: [Patient Birth Date]

Member ID: [Patient Member ID Number]

Policy or Group Number: [Patient Policy or Group Number]

Case ID Number: [Case ID Number (if available)]

To Whom It May Concern:

I understand that the [plan name] policy for [patient name] requires [restriction description] prior to approving ZYNYZ™ (retifanlimab-dlwr) treatment. However, I believe that [patient name] requires ZYNYZ without [restriction description] due to clinical and medical circumstances. Please see below for details about symptoms, previous treatments, medical history, and treatment rationale that supports the claim for medical exception for [patient name].

Patient's Clinical / Medical History

- [Patient's ICD-10-CM diagnosis code and date of diagnosis]
- [Patient's first visit date and date of referral]
- [Patient's performance status]
- [Prior treatments - drug names and duration, responses to those treatments, and reason for discontinuation]
- [Patient's disease progression]
- [Any additional factors impacting ZYNYZ treatment selection]

Justification for Medical Exception

- [State the clinical rationale for treatment with ZYNYZ]
- [Describe why the plan requirement is not appropriate for your patient]
- [List concerns (e.g., experience on similar therapies, drug side effects, other patient-specific considerations)]

Treatment Plan

- [Include plan of treatment: dosage, frequency, and length of treatment]
- [State the clinical rationale for treatment with ZYNYZ]

Summary

Based on the above, I hope you agree ZYNYZ is an appropriate treatment for [patient name]. A timely approval of ZYNYZ by [plan name] without [restriction description] would be greatly appreciated by myself and my patient. Please contact me at [phone number] if you need more information to approve this medical exception.

Sincerely,

[Physician Name]

[Physician Address]

[Physician Phone]

Enclosures: [List any applicable enclosures such as prescribing information, patient medical history, relevant peer-reviewed articles, FDA approval letter, etc.]