

[Physician Name]
[Institution/Clinic Name]
[Address]
[City, State, Zip Code]
[Email Address]
[Phone Number]

[Date]

[Name of Pharmaceutical Company]
[Attention: Expanded Access/Compassionate Use Department]
[Address]
[City, State, Zip Code]

RE: Formal Appeal for Compassionate Use Access to [Investigational Drug Name]

Patient Name: [Patient Name]
Date of Birth: [DOB]
Diagnosis: [Diagnosis Name]

To the Expanded Access Committee,

I am writing to formally appeal the recent decision to deny [Patient Name] access to [Investigational Drug Name] via your compassionate use/expanded access program. As [Patient Name]'s treating physician, I have reviewed the initial denial and believe that the clinical urgency of this case warrants a reconsideration.

Clinical Background:

The patient is currently diagnosed with [Diagnosis], which is [serious/life-threatening/severely debilitating]. To date, the patient has exhausted all FDA-approved therapies, including [list failed treatments]. There are no remaining standard-of-care options that offer a reasonable prospect of clinical benefit.

Rationale for Use:

I have reviewed the available clinical data for [Investigational Drug Name]. Based on the patient's specific biomarker profile and disease progression, I believe this investigational agent represents the only remaining viable intervention. Specifically, [provide 1-2 sentences on why this drug is scientifically appropriate for this patient].

Ineligibility for Clinical Trials:

The patient is currently ineligible for your active clinical trials because [state reason, e.g., geographic location, specific exclusion criteria, or lack of open enrollment].

Physician Commitment:

I am prepared to fulfill all regulatory requirements, including obtaining IRB approval, managing the FDA Individual Patient IND process, and providing rigorous safety monitoring and data reporting to your company.

We urge you to reconsider this request to provide [Patient Name] with a potentially life-saving opportunity. Thank you for your time and re-evaluation of this case.

Sincerely,

[Signature]

[Physician Printed Name]
[Medical License Number]
[Board Certification]