

Sample Letter of Medical Necessity

[Date]

[Name of pharmacy director or payer contact]

[Contact's title]

[Phone] | [Fax] | [Email]

[Insurance Company Name]

[Address]

Patient: [Patient's name]

Date of birth: [Patient's Date of Birth]

Insurance ID: [Patient's Insurance ID]

Policy Group: [Patient's Group Number]

Diagnosis: [Patient's Diagnosis (ICD-10: C34.XX)]

Re: Requested Treatment: IBTROZI™ (taletrectinib)

Dear [Medical/Pharmacy Director]:

I am writing on behalf of [Patient's Name] to formally document the medical necessity for treatment with IBTROZI for a diagnosis of [Patient's Diagnosis]. [If prior authorization has been submitted previously, indicate date of submission and outcome.]

IBTROZI is indicated for the treatment of adult patients with locally advanced or metastatic *ROS1*-positive non-small cell lung cancer (NSCLC). This letter provides additional information and clinical rationale in support of the medical necessity for [initiating/continuing/reinitiating] treatment with IBTROZI.

Patient Clinical History:

[Patient's Name] is a [age]-year-old [gender] who was diagnosed with [specific type of NSCLC (eg, metastatic adenocarcinoma of the lung)] on [date]. Key clinical findings include:

- Tumor Characteristics: [Histology, staging, mutations]
- Molecular Testing Results: [ROS1]
- Previous Treatments: [List chemotherapy, immunotherapy, radiation, or prior targeted therapies]
- Disease Progression: [Describe disease status, prior responses, or resistance to standard treatments]
- Performance Status: [ECOG score or Karnofsky Performance Status]
- FOR IBTROZI **INITIATION** – patients who have not been previously treated with IBTROZI: [Include a summary of your professional opinion and potential prognosis for treatment with IBTROZI] [Include clinical rationale documenting medical necessity for initiation of treatment]
- FOR IBTROZI **CONTINUATION** – patients who are currently treated with IBTROZI: [Include a summary of patient's clinical response to treatment and impact to daily life] [Include clinical rationale documenting medical necessity for continuation of treatment]
- FOR IBTROZI DOSE **WITHHOLDING** – patients who have interrupted treatment with IBTROZI: [Include dates of IBTROZI initiation and dose withholding] [Include reason for interrupting therapy] [Include a summary of the patient's condition and a clinical rationale for dose withholding IBTROZI]

Rationale for Treatment:

IBTROZI is indicated for the treatment of adult patients with locally advanced or metastatic *ROS1*-positive non-small cell lung cancer. The clinical evidence supporting its use includes: [Summarize pivotal clinical trial data (eg, overall response rate [ORR]). Given the patient's [mutation subtype, disease progression, intolerance to previous treatments], IBTROZI represents the most appropriate treatment option, [describe your clinical rationale for IBTROZI™ rather than alternative(s)].

Request for Coverage

In summary, treatment with IBTROZI is medically necessary, and I am requesting immediate authorization and coverage under [Patient's Name]'s insurance benefits. It is consistent with the current standards of care and is in accordance with the FDA-approved indication. Delaying access to this treatment could lead to disease progression and worsened prognosis.

If additional information is required, I can be reached at [Physician's Contact Information]. Thank you for your time and prompt consideration.

Sincerely,

[Physician's signature]

[Physician name] [Physician NPI] [Name of practice]

Supporting documentation to enclose in your submission: [List and attach additional documents, which may include IBTROZI prescribing information, pathology and molecular testing reports, recent clinical notes and treatment history, and published clinical trial data (if required by payer).]

Note: This example letter is provided as a courtesy and not intended to be a directive. Physicians should exercise medical judgment and discretion to appropriately diagnose and characterize the individual patient's medical condition. In addition, healthcare professionals (HCPs) are responsible for ensuring the accuracy and validity of all billing and claims for appropriate reimbursement.