Sample Letter of Medical Necessity for Itovebi™ (inavolisib)

Instructions for Use

When submitting a prior authorization (PA) request to a patient's health insurance plan, including a letter of medical necessity can help explain the rationale and clinical decision-making behind the choice to prescribe Itovebi.

Using the information in this sample letter does not guarantee that the health plan will provide reimbursement for Itovebi. It is not intended to be a substitute for, or influence on, the independent medical judgment of the physician.

Some key reminders

- Include the appropriate ICD-10-CM diagnosis code(s)
- For a list of sample coding, visit Genentech-Access.com/itovebi
- Please ensure the treating physician signs the letter
- Please refer to page 3 for the list of enclosures

[Date]

[Payer name]
Attention: [Contact title/Medical Director]
[Address]

Subject: **Letter of Medical Necessity for Itovebi™ (inavolisib)**

Patient: [Patient name]
Date of Birth: [MM/DD/YYYY]
Insurance ID number: [Insurance ID Number]
Insurance Group Number: [Insurance Group Number]
Case ID Number: [Case ID Number (if available)]
Dates of Service: [Dates]

Dear [Contact Name/Medical Director],

I'm writing on behalf of my patient, [first and last name], to [request prior authorization of/ document medical necessity for] for treatment with Itovebi™ (inavolisib). This letter provides information about the patient's medical history and diagnosis, and a summary of the treatment plan.

Patient's Clinical History

[Patient's name] is [a/an] [age]-year-old [male/female/transgender/etc.] patient who, as of [date], has been diagnosed with endocrine-resistant, PIK3CA-mutated, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, [locally advanced or metastatic breast cancer] as of [date].

This patient has been under my care since [date], having been referred to me by [referring physician's name] for [reason].

[Brief summary of rationale for treatment with Itovebi. This may include a brief description of the patient's diagnosis, including the ICD-10-CM code, the severity of the patient's condition, prior adjuvant therapy, the duration and response to that treatment, the rationale for discontinuation, as well as other factors that have affected your treatment selection.]

Treatment Plan

On October 2024, the FDA approved Itovebi in combination with palbociclib and fulvestrant for the treatment of adults with endocrine-resistant, PIK3CAmutated, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer, as detected by an FDA-approved test, following recurrence on or after completing adjuvant endocrine therapy.

[Include plan of treatment (dosage, length of treatment) and clinical practice guidelines that support the use of Itovebi. Consider mentioning experts in the field who also support the treatment.]

Summary

Based on the above facts, I believe Itovebi is not only indicated, but also medically necessary for this patient. If you have any further questions, please contact me at [phone

number] or [email address]. Thank you for your consideration.

Sincerely,

[Physician signature]
[Physician typed name and credentials]

Enclosures [List enclosures, which may include:

- Prior Authorization recommended by the health plan
- Itovebi Prescribing Information
- FDA approval letter for Itovebi
- Clinical notes/medical records
- Diagnostic test results: confirmation of PIK3CA-mutation, confirmation of HR+, HER2− mBC
- Documentation of endocrine resistance: progression during or after completing adjuvant endocrine therapy
- Documentation for the other drugs in the Itovebi regimen
- Evidence of measurable disease
- Relevant peer-reviewed articles]