



Commercial PA Criteria
Effective: December 12, 2024

Prior Authorization: Itovebi (inavolisib)

Products Affected: Itovebi (inavolisib) tablets

Medication Description: Itovebi, in combination with palbociclib and fulvestrant, is indicated for the treatment of adults with endocrine-resistant, PIK3CA-mutated, 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.

Covered Uses:

1. endocrine-resistant, PIK3CA-mutated, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer

Exclusion Criteria: None

Required Medical Information:

1. Diagnosis
2. Medical History
3. Medication History

Prescriber Restriction: The medication must be prescribed by, or in consultation with, an oncologist.

Age Restriction: Patient must be 18 years of age or greater.

Coverage Duration:

Initial: 3 months

Continuation: 6 months

Other Criteria:

Initial Approval Criteria

1. Breast Cancer. Approve if the patient meets ALL of the following (A, B, C, D, E, F, and G):

- A. Patient is ≥ 18 years of age; **AND**
- B. Patient meets ONE of the following (i or ii):
 - i. Patient is a postmenopausal female; **OR**
 - ii. Patient meets BOTH of the following (a and b):
 - a. Patient is a pre/perimenopausal female or a male; **AND**
 - b. Patient is receiving a gonadotropin-releasing hormone (GnRH) agonist; **OR**
Note: Examples of a GnRH agonist include leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous injection).
- C. Patient has locally advanced or metastatic hormone receptor (HR)-positive disease; **AND**

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- D. Patient has human epidermal growth factor receptor 2 (HER2)-negative disease; **AND**
- E. Patient has *PIK3CA*-mutated breast cancer as detected by an approved test; **AND**
- F. Patient has disease recurrence on or after completing adjuvant endocrine therapy; **AND**
Note: Examples include tamoxifen, anastrozole, letrozole, exemestane, toremifene.
- G. The medication will be used in combination with Ibrance® (palbociclib capsules and tablets) and fulvestrant injection.

References:

1. Itovebi™ tablets [prescribing information]. South San Francisco, CA: Genentech; October 2024.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	12/12/2024