

Generic Name: Inavolisib

Preferred: N/A

Therapeutic Class or Brand Name: Itovebi

Non-preferred: N/A

Applicable Drugs: N/A

Date of Origin: 6/2/2025

Date Last Reviewed / Revised: N/A

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I to V are met.)

- I. Documentation of the following diagnoses AND must meet all criteria listed under the applicable diagnosis:
FDA-Approved Indication(s)
 - A. Breast Cancer
 - i. Locally advanced or metastatic disease
 - ii. Disease is hormone receptor (HR) positive
 - iii. Disease is human epidermal growth factor receptor 2 (HER2)-negative
 - iv. Disease is PIK3CA-mutation positive
 - v. Used following recurrence on or after completing adjuvant endocrine therapy
 - vi. Used in combination with both:
 1. Ibrance (palbociclib)
 2. Fulvestrant
- II. Minimum age requirement: 18 years old or older.
- III. Treatment must be prescribed by or in consultation with an oncologist or hematologist.
- IV. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.
- V. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- N/A

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Quantities limited to 30-day supply
 - 9 mg tablets:
 - Maximum quantity of 30 tablets
 - 3 mg tablets:
 - Maximum quantity of 60 tablets

APPROVAL LENGTH

- **Authorization:** 6 months
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and does not show evidence of progressive disease.

APPENDIX

N/A

REFERENCES

1. Itovebi. Prescribing Information. Genentech USA, Inc. January 2025. Accessed March 27, 2025. www.gene.com/download/pdf/itovebi_prescribing.pdf
2. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Breast Cancer. Version 3.2025. Updated March 18, 2025. Accessed March 27, 2025. www.nccn.org/professionals/physician_gls/pdf/breast.pdf

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.