

DRUG POLICY

Itovebi™ (inavolisib)

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Itovebi is indicated in combination with palbociclib and fulvestrant 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.

Compendial Use

Recurrent unresectable breast cancer

POLICY

Required Documentation

Submission of the following information is necessary to initiate the prior authorization review:

1. Documentation of test confirming presence of PIK3CA mutation
2. Documentation of hormone receptor (HR) and human epidermal growth factor receptor 2 (HER2) status

Criteria for Initial Approval

Breast Cancer

Authorization of 12 months may be granted for treatment of endocrine-resistant, PIK3CA-mutated, HR-positive, HER2-negative locally advanced, recurrent unresectable, or metastatic breast cancer when used in combination with palbociclib and fulvestrant.

Continuation of Therapy

Breast Cancer

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication in the criteria for initial approval section, when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

Other

Itovebi (inavolisib) is considered **not medically necessary** for members who do not meet the criteria set forth above.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits Apply

Medication	Standard Limit	FDA Recommended Dosing
Itovebi (inavolisib) 9 mg tablet	28 capsules per 28 days	9 mg orally once daily in combination with palbociclib and fulvestrant.
Itovebi (inavolisib) 3 mg tablet	56 tablets per 28 days	First dose reduction: 6 mg once daily Second dose reduction: 3 mg once daily If unable to tolerate the second dose reduction level, permanently discontinue inavolisib

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

N/A

REFERENCES

- Itovebi [package insert]. South San Francisco, CA: Genentech USA, Inc.; September 2025.
- The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. Available at: <https://www.nccn.org>. Accessed November 13, 2025.

POLICY HISTORY

Policy #: 05.05.60

Original Effective Date: March 7, 2025

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