| Reference number(s) |
| --- |
| 6696-A |

# Specialty Guideline Management
# Itovebi

## Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated.Over-the-counter (OTC) products are not included unless otherwise stated.

| Brand Name | Generic Name |
| --- | --- |
| Itovebi | inavolisib |

## Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

### FDA-approved Indications[1]

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[2]

Recurrent breast cancer

All other indications are considered experimental/investigational and not medically necessary.

| Reference number(s) |
| --- |
| 6696-A |

# Documentation

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

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

# Coverage Criteria

## Breast cancer[1,2]

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

# Continuation of Therapy

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

# References


1. Itovebi [package insert]. South San Francisco, CA: Genentech USA, Inc.; October 2024.
2. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed November 12, 2024.