

Inavolisib (ITOVEBI)

Criteria for Use

August 2026

VA Pharmacy Services and National Formulary Committee

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

Exclusion Criteria

If ANY of the following are selected, the patient will NOT meet criteria for inavolisib.

- ☐ Uncontrolled hyperglycemia[^]
- ☐ Unable to evaluate and optimize fasting blood glucose
- ☐ Pregnancy
- ☐ Lactating

[^] Patients with diabetes mellitus Type 1 and Type 2 requiring ongoing anti-hyperglycemic treatment were excluded from INAVO120; fasting blood glucose < 126 mg/dL and HbA1c < 6% was required prior to start

Inclusion Criteria

All the following must be selected to meet criteria.

- ☐ HR-positive, HER2-negative (IHC 0 or 1+ or IHC 2+/ISH-) locally advanced or metastatic breast cancer
- ☐ Progressive disease on or after endocrine-based adjuvant regimen
- ☐ No prior CDK4/6 inhibitor therapy (i.e. abemaciclib, ribociclib, palbociclib)
- ☐ PIK3CA-mutation detected using an FDA-approved test
- ☐ Inavolisib to be given in combination with palbociclib and fulvestrant

Additional Inclusion Criteria

All of the following criteria must be selected to meet criteria.

- ☐ Care is provided by a VA/ VA Community Care oncology provider
- ☐ Eastern Cooperative Oncology Group (ECOG) performance status 0 - 1
- ☐ Goals of care and role of Palliative Care consult have been discussed and documented

Additional Inclusion Criteria – Select If Applicable

- ☐ For females who can become pregnant: Pregnancy must be excluded prior to receiving inavolisib
- ☐ For females who can become pregnant and males with partners who can become pregnant: Counseling provided on potential risks vs benefits of treatment and the use of effective contraception during therapy and for one week after stopping treatment
- ☐ For females who are lactating / providing breastmilk to an infant or planning to do so: Counseling provided to avoid breastfeeding during therapy.

Other Justification

- ☐ _____