UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 1462-2
Program	Prior Authorization/Notification
Medication	Itovebi™ (inavolisib)
P&T Approval Date	12/2024, 12/2025
Effective Date	3/1/2026

1. Background:

Itovebi is a kinase inhibitor 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.

Coverage Information:
Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. Coverage Criteria[a]:

A. Patients less than 19 years of age

1. **Itovebi** will be approved based on the following criterion:

   a. Patient is less than 19 years of age

Authorization will be issued for 12 months.

B. Breast Cancer

1. **Initial Authorization**

   a. **Itovebi** will be approved based on **all** of the following criteria:

      (1) Diagnosis of breast cancer

-AND-

      (2) Disease is **one** of the following:

         (a) Locally advanced
         (b) Metastatic

-AND-

(3) Disease is hormone receptor (HR)-positive

-AND-

(4) Disease is human epidermal growth factor receptor 2 (HER2)-negative

-AND-

(5) Disease is PIK3CA-mutation positive

-AND-

(6) Used following recurrence on or after completing adjuvant endocrine therapy

-AND-

(7) Used in combination with **both** of the following:

(a) Ibrance (palbociclib)
(b) Fulvestrant

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Itovebi** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Itovebi therapy

Authorization will be issued for 12 months.

C. NCCN Recommended Regimens

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limit may be in place**.**

4. References:

1. Itovebi [package insert]. South San Francisco, CA: Genentech, Inc; January 2025.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed on October 28, 2025.

Program	Prior Authorization/Notification - Itovebi™ (inavolisib)
Change Control	
Date	Change
12/2024	New program.
12/2025	Annual review. No changes to clinical coverage criteria. Updated references.