PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Itovebi Prior Authorization Policy
- Itovebi® (inavolisib tablets – Genentech)

REVIEW DATE: 10/23/2024; selected revision 11/20/2024

OVERVIEW

Itovebi, a kinase inhibitor, is indicated in combination with Ibrance® (palbociclib capsules and tablets) and fulvestrant for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, phosphatidylinositol-3-kinase (*PIK3CA*)-mutated, endocrine-resistant **locally advanced or metastatic breast cancer** in adults, as detected by an FDA-approved test following recurrence on or after completing adjuvant endocrine therapy.[1]

Fasting plasma glucose/blood glucose and hemoglobin A1c (HbA1C) should be evaluated before initiating therapy. Blood glucose should be optimized prior to therapy initiation and at regular intervals during treatment.

Guidelines

The National Comprehensive Cancer Network (NCCN) breast cancer guidelines (version 6.2024 – November 11, 2024) recommend Itovebi in combination with Ibrance and fulvestrant (category 1) for first-line therapy under "Useful in Certain Circumstances" for HR+, HER2-negative tumors with *PIK3CA* activating mutations and disease progression on adjuvant endocrine therapy or relapse within 12 months of adjuvant endocrine therapy completion.[3] The guidelines recommend Piqray® (alpelisib tablets), in combination with fulvestrant, as a "preferred" second-line regimen or subsequent-line therapy for *PIK3CA*-activating mutation in HR+/HER2-negative, recurrent unresectable (local or regional) or Stage IV disease (category 1). "Preferred" first-line regimens for HR+/HER2-negative disease, without a *PIK3CA* activating mutation, include the following: aromatase inhibitor (i.e., letrozole, anastrozole, exemestane) + CDK4/6 inhibitor (i.e., Ibrance, Kisqali® [ribociclib tablets], Verzenio® [abemaciclib tablets]) or fulvestrant + CDK4/6 inhibitor.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Itovebi. All approvals are provided for the duration noted below. In the clinical criteria, as appropriate, an asterisk (*) is noted next to the specified gender. In this context, the specified gender is defined as follows: a woman is defined as an individual with the biological traits of a woman, regardless of the individual's gender identity or gender expression; men are defined as individuals with the biological traits of a man, regardless of the individual's gender identity or gender expression.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Itovebi is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Breast Cancer.** Approve for 1 year if the patient meets ALL of the following (A, B, C, D, E, F, and G):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient meets ONE of the following (i or ii):
     - **i.** Patient is a postmenopausal female*; OR
     - **ii.** Patient is a pre/perimenopausal female* or a male* and meets ONE of the following (a or b):
       - **a)** Patient is receiving a gonadotropin-releasing hormone (GnRH) agonist; OR
         Note: Examples of a GnRH agonist include leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous injection).
       - **b)** Patient has had surgical bilateral oophorectomy or ovarian irradiation (female*) or orchiectomy (male*); AND
   - **C)** Patient has locally advanced or metastatic hormone receptor (HR)-positive disease; AND
   - **D)** Patient has human epidermal growth factor receptor 2 (HER2)-negative disease; AND
   - **E)** Patient has *PIK3CA*-mutated breast cancer as detected by an approved test; AND
   - **F)** Patient meets ONE of the following (i or ii):
     - **i.** Patient has disease progression while on adjuvant endocrine therapy; OR
     - **ii.** Patient has had disease recurrence within 12 months after completing adjuvant endocrine therapy; AND

     Note: Examples of endocrine therapy include tamoxifen, anastrozole, letrozole, exemestane, toremifene.
   - **G)** The medication will be used in combination with Ibrance® (palbociclib capsules and tablets) and fulvestrant injection.

   * Refer to Policy Statement

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Itovebi is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Itovebi™ tablets [prescribing information]. South San Francisco, CA: Genentech; October 2024.
2. The NCCN Breast Cancer Clinical Practice Guidelines in Oncology (version 6.2024 – November 11, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on November 12, 2024.