PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Ibrance Prior Authorization Policy
- Ibrance® (palbociclib capsules and tablets – Pfizer)

REVIEW DATE: 02/21/2024

OVERVIEW

Ibrance, a cyclin-dependent kinase (CDK) 4/6 inhibitor, is indicated for the treatment of hormone receptor positive (HR+), human epidermal growth factor receptor 2 (HER2)-negative **advanced or metastatic breast cancer** in adults, in combination with:[1]

- An aromatase inhibitor (AI) as initial endocrine-based therapy.
- Fulvestrant in patients with disease progression following endocrine therapy.

Guidelines

Ibrance is discussed in in guidelines from National Comprehensive Cancer Network (NCCN):

- **Breast Cancer:** NCCN guidelines (version 1.2024 – January 25, 2024) recommend Ibrance + AI or fulvestrant (category 2A) as a first-line "Preferred Regimen".[2,3] CDK4/6 inhibitor + fulvestrant is recommended for second- and subsequent-line therapy as a "Preferred Regimen", if CDK4/6 inhibitor was not previously used (category 1). However, the guidelines state in a footnote that if there is disease progression on Ibrance, there are limited phase II data to support the use of Kisqali® (ribociclib tablets) in the second-line setting.[2,3] The guidelines state that in Phase III randomized controlled trials, fulvestrant in combination with a CDK4/6 inhibitor has shown overall survival benefit in the second-line setting. The compendium recommends that men with breast cancer be treated similarly to postmenopausal women, except that the use of an AI is ineffective without concomitant suppression of testicular steroidogenesis.[3]
- **Liposarcoma:** NCCN guidelines on soft tissue sarcoma (version 3.2023 – December 12, 2023) recommend Ibrance as single-agent therapy for the treatment of unresectable retroperitoneal well-differentiated or dedifferentiated liposarcoma as "Useful In Certain Circumstances" (category 2A).[4]

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Ibrance. 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 Ibrance is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. **Breast Cancer in a Woman***. Approve for 1 year if the patient meets the following (A, B, C, D, E, and F):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has recurrent or metastatic disease; AND
   - **C)** Patient has hormone receptor positive (HR+) [i.e., estrogen receptor positive {ER+} and/or progesterone receptor positive {PR+}] disease; AND
   - **D)** Patient has human epidermal growth factor receptor 2 (HER2)-negative breast cancer; AND
   - **E)** Patient meets ONE of the following (i or ii):
     - **i.** Patient is postmenopausal; OR
     - **ii.** Patient is pre/perimenopausal and meets one of the following (a or b):
       - **a)** Patient is receiving ovarian suppression/ablation with 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; AND
   - **F)** Patient meets ONE of the following (i or ii):
     - **i.** Ibrance will be used in combination with anastrozole, exemestane, or letrozole; OR
     - **ii.** Ibrance will be used in combination with fulvestrant.

   ***** Refer to the Policy Statement.

2. **Breast Cancer in a Man*.** Approve for 1 year if the patient meets the following (A, B, C, D, and E):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has recurrent or metastatic disease; AND
   - **C)** Patient has hormone receptor positive (HR+) [i.e., estrogen receptor positive {ER+} and/or progesterone receptor positive {PR+}] disease; AND
   - **D)** Patient has human epidermal growth factor receptor 2 (HER2)-negative breast cancer; AND
   - **E)** Patient meets ONE of the following (i or ii):
     - **i.** Patient meets BOTH of the following (a and b):
       - **a)** Patient is receiving a gonadotropin-releasing hormone (GnRH) analog; AND
         Note: Examples of a GnRH analog include leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), Firmagon (degarelix acetate subcutaneous injection), Orgovyx (relugolix tablet).
       - **b)** Ibrance will be used in combination with anastrozole, exemestane, or letrozole; OR
     - **ii.** Ibrance will be used in combination with fulvestrant.

   ***** Refer to the Policy Statement.

Other Uses with Supportive Evidence

3. **Liposarcoma**. Approve for 1 year if the patient meets the following (A and B):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has well-differentiated/dedifferentiated liposarcoma.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Ibrance 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. Ibrance® capsules and tablets [prescribing information]. New York, NY: Pfizer Labs; September 2023.
2. The NCCN Breast Cancer Clinical Practice Guidelines in Oncology (version 1.2024 – January 25, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on February 19, 2024.
3. The NCCN Drugs & Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on February 19, 2024. Search terms: palbociclib.
4. The NCCN Soft Tissue Sarcoma Clinical Practice Guidelines in Oncology (version 3.2023 – December 12, 2023) © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on February 19, 2024.