VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 01/26/2022; selected revision 06/22/2022

OVERVIEW

Ibrance, a cyclin-dependent kinase (CDK) 4/6 inhibitor, is indicated for the treatment of adults with hormone receptor positive (HR+), human epidermal growth factor receptor 2 (HER2)-negative **advanced or metastatic breast cancer** 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 2.2022 –December 20, 2021) recommend any of the CDK4/6 inhibitors in combination with an AI or fulvestrant as a first-line preferred treatment option for recurrent or HR+ and HER2-negative recurrent unresectable (local or regional) Stage IV disease in postmenopausal women or premenopausal patient receiving ovarian ablation or suppression (category 1).[2,3] CDK4/6 inhibitor + fulvestrant is recommended for second- and subsequent-line therapy, if CDK4/6 inhibitor was not previously used (category 1). However, the guidelines also state in a footnote that if there is disease progression on CDK4/6 inhibitor therapy, there are limited data to support an additional line of therapy with another CDK4/6-containing regimen.[2,3] The guidelines state that in phase 3 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:** The NCCN guidelines on soft tissue sarcoma (version 2.2021 – April 28, 2021) recommend Ibrance as single-agent therapy for the treatment of well-differentiated/dedifferentiated liposarcoma for retroperitoneal sarcomas (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 Women***. Approve for 1 year if the patient meets the following criteria (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 criteria (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 criteria (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 Men*.** Approve for 1 year if the patient meets the following criteria (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 criteria (i or ii):
     - **i.** Patient meets BOTH of the following criteria (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 criteria (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; December 2022.
2. The NCCN Breast Cancer Clinical Practice Guidelines in Oncology (version 2.2022–December 20, 2021). © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 19, 2022.
3. The NCCN Drugs & Biologics Compendium. © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 19, 2022. Search terms: palbociclib.
4. The NCCN Soft Tissue Sarcoma Clinical Practice Guidelines in Oncology (version 2.2021–April 28, 2021) © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 19, 2022.

HISTORY

Type of Revision	Summary of Changes	Review Date
Early Annual Revision	**All Breast Cancer Indications:** Deleted criteria requiring no disease progression on Kisqali (ribociclib), Ibrance, or Verzenio (abemaciclib), based on guidelines and available data. **Breast Cancer in Pre/Perimenopausal Women:** Examples of gonadotropin-releasing hormone (GnRH) agonists are moved from criteria to Note. **Breast Cancer in Men:** GnRH "agonist" is changed to "analog". Also, the list of examples of GnRH analog agents are moved from criteria to Note. Firmagon (degarelix) and Orgovyx (relugolix) were added to example list.	02/24/2021
Annual Revision	**Breast Cancer in Women:** The word "postmenopausal" was moved from the condition of approval and added into the criteria. Criteria for pre/perimenopausal women was added: patient is receiving ovarian suppression/ablation with a GnRH agonist OR patient has had surgical bilateral oophorectomy or ovarian irradiation; and a note with examples of GnRH agonists were added. The requirement that the patient has "advanced or metastatic disease" was changed to "recurrent and metastatic disease" and a requirement was added that the patient is ≥ 18 years of age. **Breast Cancer in Pre/Perimenopausal Women:** This condition of approval was removed and rolled into Breast Cancer in Women. **Breast Cancer in Men**: The requirement that the patient has "advanced or metastatic disease" was changed to "recurrent and metastatic disease," and a requirement was added that the patient is ≥ 18 years of age. **Liposarcoma**. A requirement was added that the patient is ≥ 18 years of age.	01/26/2022
Selected Revision	**Breast Cancer in Women:** The duration of approval was changed from 3 years to 1 year. **Breast Cancer in Men:** The duration of approval was changed from 3 years to 1 year. **Liposarcoma:** The duration of approval was changed from 3 years to 1 year.	06/22/2022
Update	**12/28/2022**: The overview section was updated with a change in the FDA labeled indication for breast cancer. The following, "an aromatase inhibitor (AI) as initial endocrine-based therapy in postmenopausal women or in men" was changed to, "an aromatase inhibitor (AI) as initial endocrine-based therapy."	--

GnRH – Gonadotropin- releasing hormone.