MEDICAL MUTUAL®

Drug Policy

Policy:	Ibrance (palbociclib)	Annual Review Date: 06/15/2023 Last Revised Date: 06/15/2023

OVERVIEW

Ibrance is a kinase inhibitor approved for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in combination with letrozole as initial endocrine based therapy in postmenopausal women, or in combination with fulvestrant in women with disease progression following endocrine therapy. The indication in combination with letrozole is approved under accelerated approval based on progression-free survival (PFS). Full approval has been granted based on the results of the confirmatory Phase 3 PALOMA-2 trial.

POLICY STATEMENT

This policy involves the use of Ibrance. Prior authorization is recommended for pharmacy benefit coverage of Ibrance. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Ibrance as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Ibrance be prescribed by or in consultation with a physician who specializes in the condition being treated. In order to be considered for coverage, Ibrance must be prescribed by or in consultation with a hematologist or oncologist. All approvals for initial therapy are provided for the initial approval duration noted below.

RECOMMENDED AUTHORIZATION CRITERIA

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

For All Breast Cancer Indications: Approvals will be granted if the indication-specific criteria listed below is met AND the patient meets ONE of the below criteria. If the patient does not meet any of the following, offer to review for one of the preferred products (Verzenio, Kisqali, or Kisqali Femara Co-Pack) using the appropriate *Prior Authorization Policy.*

a) The patient has previously tried one of Kisqali, Kisqali Femara Co-Pack, or Verzenio; OR
b) The patient has been taking Ibrance and is continuing therapy **[documentation required]**

1. <u>Breast Cancer in Women</u>

Criteria. *Patient must meet the following criteria (A, B <u>and</u> C):*

A. The patient has recurrent, advanced, or metastatic hormone receptor positive (HR+) [i.e., estrogen receptor positive- {ER+} and/or progesterone receptor positive {PR+}] disease; AND
B. The patient has human epidermal growth factor receptor 2 (HER2)-negative breast cancer; AND
C. The patient meets ONE of the following criteria (a OR b):
- **a.** The patient is postmenopausal and the meets one of the following (i OR ii):
  - **i.** Ibrance will be used as first-line endocrine therapy in combination with anastrazole, exemestane, letrozole, OR fulvestrant; OR
  - **ii.** Ibrance will be used as second-line or subsequent endocrine therapy in combination with fulvestrant AND a CDK4/6 inhibitor has not been used previously; OR
- **b.** The patient is premenopausal or perimenopausal and meets the following (i AND ii):
  - **i.** The patient is receiving ovarian suppression/ablation with a gonadotropin-releasing hormone (GNRH) agonist (e.g. Lupron, Trelstar, Zoladex, surgical bilateral oophorectomy, ovarian radiation); AND
  - **ii.** One of the following is met (1 or 2):
    1. Ibrance will be used as first-line endocrine therapy in combination with anastrazole, exemestane, letrozole, or fulvestrant; OR
    2. Ibrance will be used as second-line or subsequent endocrine therapy in combination with fulvestrant AND a CDK4/6 inhibitor has not been used previously.

2. Breast Cancer in Men
Criteria. *Patient must meet the following criteria (A, B, C, and D):*

A. The patient has recurrent, advanced, or metastatic hormone receptor positive (HR+) [i.e., estrogen receptor positive- {ER+} and/or progesterone receptor positive {PR+}] disease; AND
B. The patient has human epidermal growth factor receptor 2 (HER2)-negative breast cancer; AND
C. The patient is receiving concomitant therapy with a gonadotropin-releasing hormone (GNRH) agonist (e.g. Lupron, Trelstar, Zoladex); AND
D. The patient meets ONE of the following:
- **a.** Ibrance will be used as first-line endocrine therapy in combination with anastrazole, exemestane, letrozole, or fulvestrant; OR
- **b.** Ibrance will be used as second-line or subsequent endocrine therapy in combination with fulvestrant AND a CDK4/6 inhibitor has not been used previously.

3. Well-Differentiated/Dedifferentiated Liposarcoma (WD-DDLS)
Criteria. *Approve if Ibrance will be used as a single agent and patient has unresectable disease of the retroperitoneum.*

4. Patients with another indication that is not listed but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation
Criteria. *Prescriber will provide specific diagnosis for documentation. Approve.*

5. Patient has been started on Ibrance
Criteria. *Approve for an indication or condition addressed as an approval in this document.*

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Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year
B) *Extended Approval:* 1 year

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Ibrance has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

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

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Ibrance capsules [prescribing information]. New York, NY: Pfizer Labs; December 2022.
2. Ibrance tablets [prescribing information]. New York, NY: Pfizer Labs; December 2022.
3. Finn RS, Martin M, Rugo HS, et al. Palbociclib and letrozole in advanced breast cancer. N Engl J Med. 2016; 375(20):1925-1936.
4. Palbociclib. In: DRUGDEX (online database). Truven Health Analytics: Greenwood Village, CO. Last updated 20 June 2023. Accessed on 23 June 2023.
5. The NCCN Drugs and Biologics Compendium. © 2023 National Comprehensive Cancer Network, Inc. Available at http://www.nccn.org . Accessed on 22 June 2023.