Generic Name: palbociclib

Therapeutic Class or Brand Name: Ibrance

Applicable Drugs: N/A

Preferred: N/A

Non-preferred: N/A

Date of Origin: 9/8/2025

Date Last Reviewed / Revised: N/A

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I to V are met.)

I. Documentation of the following diagnosis AND must meet all criteria listed under the applicable diagnosis:

FDA-Approved Indication(s)

A. Breast cancer

i. Documentation of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer

ii. Documentation of advanced or metastatic disease and meets one of the following (1, 2, or 3):

1. Used with an aromatase inhibitor inhibitor (ex: anastrazole, letrozole, exemestane) as initial endocrine-based therapy

2. Used with fulvestrant

a. Disease has progressed following endocrine-based therapy

3. Documentation of PIK3CA-mutatation

a. Disease has progressed on or after completing adjuvant endocrine therapy

b. Used in combination with Itovebi (inavolisib) and fulvestrant

II. Minimum age requirement: 18 years old.

III. Treatment must be prescribed by or in consultation with an oncologist or hematologist.

IV. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

V. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- The patient has had no prior treatment with a CDK4/6 inhibitor (i.e. Ibrance [palbociclib], Kisqali [ribociclib], or Verzenio [abemaciclib]) resulting in disease progression.

OTHER CRITERIA

- Pre/peri-menopausal women treated with the combination of Ibrance plus an aromatase inhibitor or fulvestrant or Ibrance plus Itovebi (inavolisib) plus fulvestrant should be treated with a luteinizing hormone-releasing hormone (LHRH) agonist (ex: Zoladex [goserelin], Lupron [leuprolide], etc.).

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Quantities limited to a 28-day supply (21 capsules per 28 days)
- Maximum dose: 125 mg once daily for 21 consecutive days followed by 7 days off

APPROVAL LENGTH

- **Authorization:** 1 year
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and does not show evidence of progressive disease.

APPENDIX

N/A

REFERENCES

1. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Breast Cancer. Version 4.2025. Updated April 17, 2025. Accessed July 10, 2025. www.nccn.org/professionals/physician_gls/pdf/breast.pdf
2. Ibrance. Prescribing Information. Pfizer Inc. April 2025. Accessed July 10, 2025. www.access.fda.gov/drugsatfda_docs/label/2025/207103s020lbl.pdf