Applicable Drugs: Ibrance (palbociclib)

Preferred: N/A

Non-preferred: N/A

Date of Origin: 9/8/2025

Date Last Reviewed / Revised: 7/27/2026

PRIOR AUTHORIZATION CRITERIA

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

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

FDA-Approved Indication(s)

A. Breast cancer

i. Documentation of advanced or metastatic disease

1. Documentation of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative disease and meets one of the following (a, b, or c):

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

b. Used with fulvestrant

i. Disease has progressed following endocrine-based therapy

c. Documentation of PIK3CA-mutatation

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

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

2. Documentation of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-positive disease

a. Used in combination with trastuzumab, with or without pertuzumab and endocrine therapy

b. Used for maintenance treatment following induction treatment

Other Uses With Supportive Evidence

B. Soft tissue sarcoma

C. Uterine cancer

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 National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1 or 2A..

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 or tablets 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 5.2026. Updated July 7, 2026. Accessed July 27, 2026. www.nccn.org/professionals/physician_gls/pdf/breast.pdf
2. Ibrance capsules. Prescribing Information. Pfizer Inc. 2026. Accessed July 27, 2026. labeling.pfizer.com/ShowLabeling.aspx?id=2191

3. Ibrance tablets. Prescribing Information. Pfizer Inc. 2026. Accessed July 27, 2026. labeling.pfizer.com/ShowLabeling.aspx?id=12921
4. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Soft Tissue Sarcoma. Version 5.2026. Updated July 23, 2026. Accessed July 27, 2026. www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf
5. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Uterine Neoplasms. Version 3.2026. Updated June 16, 2026. Accessed July 27, 2026. www.nccn.org/professionals/physician_gls/pdf/uterine.pdf

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.