Ibrance (palbociclib)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Ibrance (palbociclib)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Ibrance (palbociclib) may be approved if the following criteria are met:

I. Individual has a diagnosis of advanced, recurrent unresectable, or metastatic breast cancer with hormone receptor-positive, human epidermal growth factor receptor 2-negative (HR+/HER2-) disease (capsule or tablet);
AND

II. Individual is one of the following (NCCN 2A):
   A. Male; **OR**
   B. Postmenopausal female; **OR**
   C. Premenopausal treated with ovarian ablation/suppression;
AND

III. Individual is using in one of the following ways:
   A. Individual is using in combination with an aromatase inhibitor as initial endocrine therapy (Label); **OR**
   B. Individual is using in combination with fulvestrant as initial endocrine therapy (NCCN 1); **OR**
   C. Individual is using in combination with fulvestrant (Faslodex) with disease progression following endocrine therapy (Label, NCCN 1);

OR

IV. Individual has a diagnosis of Soft Tissue Sarcoma with unresectable Well Differentiated/Dedifferentiated Liposarcoma (WD-DDLS) of the retroperitoneum (capsule only) (NCCN 2A); **AND**
   A. Individual is using Ibrance as a single agent.

OR

V. Individual has a diagnosis of locally advanced or metastatic breast cancer (Label, NCCN 1); **AND**

VI. Individual is HR-positive, HER2-negative (HR+/HER2 -) (defined as IHC 0 or 1+ or IHC 2+/ISH-); **AND**

VII. Individual has endocrine-resistant breast cancer; **AND**

VIII. Individual has PIK3CA biomarker mutation; **AND**

IX. Individual is using in combination with inavolisib (Itovebi) and fulvestrant; **AND**

X. Individual is using following recurrence on or after completing adjuvant endocrine therapy; **AND**
XI. Individual has a HbA1C < 6%; **AND**
XII. Individual has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 1.

Key References:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: Updated periodically.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2025; Updated periodically.
4. Verzenio (abemaciclib) [prescribing information]. Indianapolis, IN: Lilly USA, LLC; October 2021.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2025 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on April 3, 2025.
    a. Breast Cancer. V3.2025. Revised March 18, 2025
    b. Soft Tissue Sarcoma. V5.2024. Revised March 10, 2025.
    c. Uterine Neoplasms. V3.2025. Revised March 7, 2025.