Ibrance (palbociclib)

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

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, 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).

Key References:

- 1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2023. URL: http://www.clinicalpharmacology.com. Updated periodically.
- 2. 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.
- 3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
- 4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
- 5. NCCN Clinical Practice Guidelines in Oncology™. © 2023 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on March 30, 2021.
- 6. Breast Cancer. V4.2023. Revised March 23, 2023.
- 7. Soft Tissue Sarcoma. V1.2023. Revised March 13, 2023.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.

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