

SPECIALTY GUIDELINE MANAGEMENT

IBRANCE (palbociclib)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications

Ibrance is indicated for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in combination with:

1. an aromatase inhibitor as initial endocrine based therapy in postmenopausal women, or
2. fulvestrant in women with disease progression following endocrine therapy.

B. Compendial Uses

Soft tissue sarcoma: well-differentiated/dedifferentiated liposarcoma-

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

A. **Breast cancer**

Authorization of 12 months may be granted for the treatment of HR-positive HER2-negative breast cancer when one of the following criteria is met:

1. Ibrance is used in combination with an aromatase inhibitor (eg, anastrozole, exemestane, letrozole).
2. Ibrance is used in combination with fulvestrant.

B. **Soft tissue sarcoma**

Authorization of 12 months may be granted for treatment of well-differentiated/dedifferentiated liposarcoma.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

IV. REFERENCES

1. Ibrance [package insert]. New York, NY: Pfizer Inc.; March 2017.
2. The NCCN Drugs & Biologics Compendium® © 2017 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed January 16, 2018.

3. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Breast Cancer. Version 2. 2016.
http://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed January 16, 2018.