Reference number(s)
1726-A

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 in men, or
2. fulvestrant in patients with disease progression following endocrine therapy.

B. Compendial Uses
1. Breast cancer: Therapy for recurrent HR-positive, HER2-negative disease
2. Soft tissue sarcoma: Single-agent therapy for unresectable well-differentiated/dedifferentiated liposarcoma of the retroperitoneum.

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of hormone receptor (HR) and human epidermal growth factor receptor 2 (HER2) status is necessary to initiate the prior authorization review, where applicable.

III. CRITERIA FOR INITIAL APPROVAL

A. Breast cancer
Authorization of 12 months may be granted for treatment of HR-positive, HER2-negative recurrent, advanced, or metastatic breast cancer when one of the following criteria is met:
1. Ibrance is used in combination with an aromatase inhibitor (e.g., 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 unresectable well-differentiated/dedifferentiated liposarcoma of the retroperitoneum when used as a single agent.

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication outlined in section III when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

V. REFERENCES

1. Ibrance capsules [package insert]. New York, NY: Pfizer Inc.; September 2019.
2. Ibrance tablets [package insert]. New York, NY: Pfizer Inc.; November 2019.
3. The NCCN Drugs & Biologics Compendium® © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed November 24, 2020.
4. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Soft Tissue Sarcoma. Version 1.2021. http://www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf. Accessed November 24, 2020.