BlueCross BlueShield Federal Employee Program

IBRANCE
(palbociclib)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Ibrance (Palbociclib) is an inhibitor of cyclin-dependent kinases (CDK) 4 and 6. Cyclin D1 and CDK4/6 are downstream of signaling pathways which lead to cellular proliferation. Ibrance is used for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer. Ibrance is also used off-label for the treatment of well-differentiated/dedifferentiated liposarcoma (WD-DDLS) (1-2).

Regulatory Status

FDA-approved indication: Ibrance is a kinase inhibitor indicated: (1)

- for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in combination with:
  - an aromatase inhibitor as initial endocrine-based therapy; or
  - fulvestrant in patients with disease progression following endocrine therapy.
- in combination with inavolisib and fulvestrant for the treatment of adult patients with endocrine-resistant, *PIK3CA*-mutated, HR-positive, HER2-negative, locally advanced or metastatic breast cancer, as detected by an FDA-approved test, following recurrence on or after completing adjuvant endocrine therapy.

Off-Label Use: (2)

The National Comprehensive Cancer Network (NCCN) recommend the use of Ibrance in males with estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced breast cancer and for well-differentiated/dedifferentiated liposarcoma (WD-DDLS) per the NCCN guidelines.

The safety and effectiveness of Ibrance have not been established in pediatric patients (1).

Summary

Ibrance is a prescription medicine that is used for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer. Ibrance is also used off-label for the treatment of well-differentiated/dedifferentiated liposarcoma (WD-DDLS). The safety and effectiveness of Ibrance have not been established in pediatric patients (1-2).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Ibrance while maintaining optimal therapeutic outcomes.

References

1. Ibrance [package insert]. New York, NY; Pfizer Labs; April 2024.
2. NCCN Drugs & Biologics Compendium® Palbociclib 2025. National Comprehensive Cancer Network, Inc. Accessed on January 8, 2025.