Reference number(s)
1726-A

Specialty Guideline Management
Ibrance

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Ibrance	palbociclib

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.

FDA-Approved Indications[1,2]

Ibrance is indicated for the treatment of adult patients with 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.

Compendial Uses[3,4]

- Breast cancer: Therapy for recurrent HR-positive, HER2-negative disease
- Breast cancer: Therapy for endocrine-resistant, PIK3CA-mutated, HR-positive, HER2-negative locally advanced, recurrent, or metastatic disease when used in combination with inavolisib and fulvestrant.

- Soft tissue sarcoma: Single-agent therapy for unresectable retroperitoneal well-differentiated/dedifferentiated liposarcoma

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

Documentation

Submission of the following is necessary to initiate the prior authorization review:

- Documentation of hormone receptor (HR) and human epidermal growth factor receptor 2 (HER2) status, where applicable.
- Documentation of test confirming presence of PIK3CA mutation, where applicable.

Coverage Criteria

Breast Cancer[1-4]

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:

- The requested medication is used in combination with an aromatase inhibitor (e.g., anastrozole, exemestane, letrozole).
- The requested medication is used in combination with fulvestrant.

Authorization of 12 months may be granted for treatment of endocrine-resistant, PIK3CA-mutated, HR-positive, HER2-negative locally advanced, recurrent, or metastatic breast cancer when used in combination with inavolisib and fulvestrant.

Soft Tissue Sarcoma[3]

Authorization of 12 months may be granted for treatment of unresectable retroperitoneal well-differentiated/dedifferentiated liposarcoma when used as a single agent.

Continuation of Therapy

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

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References

1. Ibrance capsules [package insert]. New York, NY: Pfizer Inc.; September 2023.
2. Ibrance tablets [package insert]. New York, NY: Pfizer Inc.; September 2023.
3. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed November 12, 2024.
4. Itovebi [package insert]. South San Francisco, CA: Genentech USA, Inc.; October 2024.