



Federal Employee Program.

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## 5.21.054

<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	July 1, 2025
<b>Subsection:</b>	Antineoplastic Agents	<b>Original Policy Date:</b>	February 20, 2015
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**Last Review Date:** June 12, 2025

### Ibrance

#### Description

#### Ibrance (palbociclib)

#### 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)-

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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).

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### Related policies

Kisqali, Verzenio

#### Policy

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

Ibrance may be considered **medically necessary** if the conditions indicated below are met.

Ibrance may be considered **investigational** for all other indications.

### Prior-Approval Requirements

**Age** 18 years of age or older

#### Diagnoses

Patient must have the following:

1. Advanced or metastatic breast cancer

**AND ONE** of the following:

- a. Patients has a *PIK3CA*-mutation as detected by an FDA approved test
  - i. Breast cancer is endocrine-resistant
  - ii. Used in combination with inavolisib and fulvestrant
  - iii. Patient has experienced recurrence on or after completing adjuvant endocrine therapy
- b. Patient is **NOT** *PIK3CA*-mutated
  - i. Used in combination with an aromatase inhibitor or fulvestrant

**AND ALL** of the following:

- a. Hormone receptor (HR)-positive
- b. Human epidermal growth factor receptor 2 (HER2)-negative

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- c. Males must have concomitant suppression of testicular steroidogenesis

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**Age** 18 years of age or older

**Diagnosis**

Patient must have the following:

1. Well-Differentiated/Dedifferentiated Liposarcoma (WD-DDLS)

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## Prior – Approval Renewal Requirements

**Age** 18 years of age or older

**Diagnoses**

Patient must have the following:

1. Advanced or metastatic breast cancer

**AND ONE** of the following:

- a. Patient has a *PIK3CA*-mutation
  - i. Used in combination with inavolisib and fulvestrant
- b. Patient is **NOT** *PIK3CA*-mutated
  - i. Used in combination with an aromatase inhibitor or fulvestrant

**AND ALL** of the following:

- a. Males must have concomitant suppression of testicular steroidogenesis
- b. **NO** disease progression or unacceptable toxicity

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**Age** 18 years of age or older

**Diagnosis**

Patient must have the following:

1. Well-Differentiated/Dedifferentiated Liposarcoma (WD-DDLS)

**AND** the following:

- a. **NO** disease progression or unacceptable toxicity

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## Policy Guidelines

### Pre – PA Allowance

None

### Prior - Approval Limits

**Duration** 12 months

### Prior – Approval Renewal Limits

Same as above

## Rationale

### 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 May 8, 2025.

## Policy History

Date	Action
February 2015	New addition to PA
March 2015	Annual editorial review and reference update
June 2015	Annual review
February 2016	Addition of males with breast cancer and the change from used in combination letrozole to aromatase inhibitor or fulvestrant (Faslodex)

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	Addition of new indication Well-Differentiated/ Dediifferentiated Liposarcoma (WD-DDLS) and metastatic breast cancer.
	Addition of no disease progression or unacceptable toxicity in renewal section
	Policy change from 5.04.54 to 5.21.54
June 2016	Annual review
June 2017	Annual editorial review and reference update
	Addition of age limit in the renewal section
December 2017	Annual review
March 2018	Annual review
June 2019	Annual editorial review and reference update
December 2019	Annual review and reference update
March 2020	Annual review and reference update
June 2020	Annual review and reference update
September 2020	Annual review
June 2021	Annual review and reference update
June 2022	Annual review and reference update
September 2022	Annual review and reference update
June 2023	Annual editorial review and reference update. Rearranged requirements for clarity
March 2024	Annual review and reference update
June 2024	Annual review and reference update
March 2025	Annual review and reference update
May 2025	Per PI update, added indication of endocrine-resistant, <i>PIK3CA</i> -mutated, HR-positive, HER2-negative locally advanced or metastatic breast cancer
June 2025	Annual review and reference update

## Keywords

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This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 12, 2025 and is effective on July 1, 2025.