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Section:	Prescription Drugs	**Effective Date:**	July 1, 2024
Subsection:	Antineoplastic Agents	**Original Policy Date:**	February 20, 2015
Subject:	Ibrance	**Page:**	1 of 5

Last Review Date: June 13, 2024

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 along with an aromatase inhibitor or fulvestrant for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer (1).

Regulatory Status
FDA-approved indication: Ibrance is a kinase inhibitor 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; or
- Fulvestrant in patients with disease progression following 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. Also Ibrance can be used with fulvestrant (Faslodex) for the treatment of postmenopausal women with estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced breast cancer as seen in the PALOMA3 study which showed that palbociclib with fulvestrant resulted in longer progression-free survival

and a relatively higher quality of life than fulvestrant alone in patients with advanced hormone-receptor–positive breast cancer that had progressed during prior endocrine therapy.

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

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 **ONE** of the following:

1. Advanced breast cancer
2. Metastatic breast cancer

AND ALL of the following:

a. Males must have concomitant suppression of testicular steroidogensis
b. Hormone receptor (HR)-positive
c. Human epidermal growth factor receptor 2 (HER2)-negative
d. Used in combination with an aromatase inhibitor or fulvestrant

Age 18 years of age or older

Diagnosis

Patient must have the following:

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

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Advanced breast cancer
2. Metastatic breast cancer

AND ALL of the following:

a. Used in combination with an aromatase inhibitor or fulvestrant
b. Males must have concomitant suppression of testicular steroidogensis
c. **NO** disease progression or unacceptable toxicity

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

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 along with aromatase inhibitor or fulvestrant (Faslodex) 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).

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; September 2023.
2. NCCN Drugs & Biologics Compendium® Palbociclib 2024. National Comprehensive Cancer Network, Inc. Accessed on April 30, 2024.

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) Addition of new indication Well-Differentiated/ Dedifferentiated 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

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 13, 2024 and is effective on July 1, 2024.