Ibrance

Description

Ibrance (palbociclib)

Background
Ibrance is a prescription medicine that is used along with aromatase inhibitor or fulvestrant (Faslodex) for the treatment of males and postmenopausal women with estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced breast cancer as the first hormone-based therapy for their metastatic disease.(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 in postmenopausal women or in men; 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

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 for patients 18 years of age or older with advanced or metastatic breast cancer or well-differentiated/ dedifferentiated liposarcoma (WD-DDLS) and if the conditions indicated below are met.

Ibrance is considered investigational for patients under the age of 18 years and for all other diagnoses.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

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 aromatase inhibitor or fulvestrant (Faslodex)

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

Prior – Approval Renewal Requirements
**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 males and postmenopausal women with estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced breast cancer as the first hormone-based therapy for their metastatic disease (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 2019.

Policy History

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<tr>
<th>Date</th>
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<tr>
<td>February 2015</td>
<td>New Addition to PA</td>
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<td>March 2015</td>
<td>Annual editorial review and reference update</td>
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<td>June 2015</td>
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<tr>
<td>February 2016</td>
<td>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</td>
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Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 6, 2019 and is effective on January 1, 2020.