UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Ibrance

Program	Prior Authorization
Medication	Ibrance® (palbociclib)
Markets in Scope	Arizona, California, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Rhode Island, Pennsylvania-CHIP, South Carolina
Issue Date	6/2015
Pharmacy and Therapeutics Approval Date	5/2020
Effective Date	7/2020

1. Background:

Ibrance® (palbociclib) 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 an aromatase inhibitor as initial endocrine-based therapy for postmenopausal women or in men, or in combination with fulvestrant in patients with disease progression following endocrine therapy.

The National Comprehensive Cancer Network (NCCN) also recommends the use of Ibrance similarly for men and premenopausal women receiving ovarian ablation/suppression with recurrent or metastatic HR-positive HER2-negative breast cancer, in combination with an aromatase inhibitor or Faslodex. The use of an aromatase inhibitor in men with breast cancer is ineffective without concomitant suppression of testicular steroidogenesis. NCCN also recommends the use of Ibrance as single-agent therapy for unresectable well-differentiated/dedifferentiated liposarcoma (WD-DDLS).

2. Coverage Criteria:

A. <u>Breast Cancer</u>

1. <u>Initial Authorization</u>

a. Ibrance will be approved based on **<u>all</u>** of the following criteria:

(1) Diagnosis of advanced, recurrent, or metastatic breast cancer

-AND-

(2) Disease is hormone-receptor (HR)-positive

-AND-

(3) Disease is human epidermal growth factor receptor 2 (HER2)-negative

-AND-

(4) **One** of the following:

(a) Used in combination with an aromatase inhibitor (e.g., anastrozole, letrozole, exemestane)

-OR-

(b) Used in combination with Faslodex (fulvestrant)

Authorization will be issued for 12 months.

2. Reauthorization

a. Ibrance will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Ibrance therapy

Authorization will be issued for 12 months.

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

1. Initial Authorization

a. Ibrance will be approved based on the following criterion:

(1) Diagnosis of unresectable WD-DDLS

Authorization will be issued for 12 months.

2. Reauthorization

a. Ibrance will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Ibrance therapy

Authorization will be issued for 12 months.

C. NCCN Recommended Regimens

1. Initial Authorization

a. **Ibrance** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Authorization will be issued for 12 months.

2. Reauthorization

a. **Ibrance** will be approved based on the following criterion:

(1) Documentation of positive clinical response to Ibrance therapy

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Ibrance [package insert]. New York, NY: Pfizer Labs; September 2019.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed April 14, 2020.

Program	Program type – Prior Authorization
Change Control	
Date	Change
6/18/2015	New Policy
10/1/2016	Updated breast cancer section to include for the disease to be recurrent or Stage IV. Updated criteria to include new indication for combination use with fulvestrant with disease progression following endocrine therapy. Updated criteria to include NCCN recommended use as a single agent for WD-DDLS. Removed prescriber requirement.
2/2017	Removed duplicate statement regarding disease progression following endocrine therapy from breast cancer section.

3/2017	Annual review. Updated references and formatting.
5/2017	Updated background and criteria to include new indication for combination use with an aromatase inhibitor as opposed to letrozole alone. Updated formatting and references.
4/2018	Minor language/formatting change to Breast Cancer section. Added NCCN Recommended Regimen review criteria. Updated references.
5/2019	Updated coverage criteria to allow for in recurrent breast cancer, added requirement of unresectable WD-DDLS, and removed disease progression following endocrine therapy criteria per NCCN recommendations. Updated background and references.
5/2020	Annual review. Updated coverage criteria for WD-DDLS per NCCN recommendations. Updated background and references.