UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 1154-13
Program	Prior Authorization/Notification
Medication	Ibrance® (palbociclib)
P&T Approval Date	4/2015, 4/2016, 3/2017, 5/2017, 5/2018, 5/2019, 5/2020, 5/2021, 5/2022, 2/2023, 2/2024, 2/2025
Effective Date	5/1/2025

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, or in combination with Faslodex® (fulvestrant) in patients with disease progression following endocrine therapy.

The use of an aromatase inhibitor in men with breast cancer is ineffective without concomitant suppression of testicular steroidogenesis. The National Comprehensive Cancer Network (NCCN) recommends the use of Ibrance as single-agent therapy for unresectable retroperitoneal well-differentiated/dedifferentiated liposarcoma (WD-DDLS).

Coverage Information:
Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. Coverage Criteria[a]:

A. <u>Patients less than 19 years of age</u>

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

   a. Patient is less than 19 years of age

   Authorization will be issued for 12 months.

B. <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.

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

1. **Initial Authorization**

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

(1) Diagnosis of unresectable retroperitoneal 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.

D. NCCN Recommended Regimens

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

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 capsules [package insert]. New York, NY: Pfizer Labs; September 2023.
2. Ibrance tablets [package insert]. New York, NY: Pfizer Labs; September 2023.
3. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed December 26, 2024.

Program	Prior Authorization/Notification – Ibrance (palbociclib)
Change Control	
4/2015	New program.
4/2016	Annual review. Updated background and criteria to include new indication for combination use with fulvestrant and NCCN recommended use as a single agent for WD-DDLS.
1/2017	Administrative change to correct spacing.
3/2017	Annual review. Change Member to Patient in Coverage Criterion. Updated 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 reference.
5/2018	Annual review. Updated background information without change to clinical intent. Updated references.
5/2019	Annual review. 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.
5/2021	Annual review. No changes to coverage criteria. Updated references.
5/2022	Annual review. No changed to coverage criteria. Updated references.
2/2023	Updated background to include pre-/perimenopausal women per FDA label. Added stated mandate and updated references.
2/2024	Annual review. Specified type of unresectable WD-DDLS to be retroperitoneal per NCCN recommendation. Updated references to separate out package insert references for Ibrance capsules and tablets.
2/2025	Annual review. No changes to clinical criteria.