Clinical Policy: Palbociclib (Ibrance)

Reference Number: CP.PHAR.125
Effective Date: 10.15
Last Review Date: 02.18
Line of Business: Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Palbociclib (Ibrance®) is an inhibitor of cyclin-dependent kinases 4 and 6.

FDA Approved Indication(s)

Ibrance is 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 in postmenopausal women; or
- Fulvestrant in women with disease progression following endocrine therapy.

Policy/Criteria

Provider must submit documentation (including such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Ibrance is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Breast Cancer (must meet all)**:**

1. Diagnosis of breast cancer;
2. Prescribed by or in consultation with an oncologist;
3. Disease meets all of the following characteristics (a, b, and c):
   a. HR-positive (i.e., estrogen receptor (ER) and/or progesterone receptor (PR) positive);
   b. HER2-negative;
   c. Disease is advanced or metastatic;
4. Prescribed for use in one of the following ways (a or b):
   a. FDA approved use (i or ii):
      i. In combination with an aromatase inhibitor (e.g., letrozole, anastrozole, exemestane) as initial endocrine-based therapy in postmenopausal women;
      ii. In combination with fulvestrant in women with disease progression following endocrine therapy;
   b. Off-label NCCN recommended use (i or ii):
      i. In combination with an aromatase inhibitor (e.g., letrozole, anastrozole, exemestane) as initial endocrine-based therapy in men who will receive concomitant treatment for suppression of testicular steroidogenesis;

ii. In combination with fulvestrant in men with disease progression following endocrine therapy;

5. Request meets one of the following (a or b):
   a. Dose does not exceed 125 mg/day (1 tablet/day for 21 days);
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

B. Soft Tissue Sarcoma (off-label) (must meet all):
1. Diagnosis of retroperitoneal well-differentiated/dedifferentiated liposarcoma;
2. Disease is unresectable, metastatic, or progressive;
3. Will be used as a single agent;
4. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

C. Other diagnoses/indications:
1. Refer to CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Breast Cancer (must meet all)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions, or documentation supports that member is currently receiving Ibrance for breast cancer and has received this medication for at least 30 days;
2. Member is responding positively to therapy without the following reasons to discontinue (a or b):
   a. Disease progression or unacceptable toxicity;
   b. Required dose reduction to < 75 mg/day;
3. Request meets one of the following (a or b):
   a. Dose does not exceed 125 mg/day (1 tablet/day for 21 days);
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

B. Soft Tissue Sarcoma (off-label) (must meet all)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions, or documentation supports that member is currently receiving Ibrance for retroperitoneal well-differentiated/dedifferentiated liposarcoma and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):
   a. New dose does not exceed 125 mg/day (1 tablet/day for 21 days).
   b. New does is supported by practice guideline or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

C. **Other diagnoses/indications** (must meet 1 or 2)**:**
   1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
      Approval duration: Duration of request or 6 months (whichever is less); or
   2. Refer to CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – CP.PMN.53 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ER/PR: estrogen receptor/progesterone receptor
FDA: Food and Drug Administration
HER2: human epidermal growth factor receptor 2
HR: hormone receptor
NCCN: National Comprehensive Cancer Network

Appendix B: Therapeutic Alternatives

Not applicable

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Breast cancer	125 mg PO QD for 21 consecutive days followed by 7 days off treatment, in combination with an aromatase inhibitor or fulvestrant	125 mg/day

VI. Product Availability

Capsules: 75 mg, 100 mg, 125 mg

VII. References

1. Ibrance Prescribing Information. New York, NY; Pfizer Labs; March 2017. Available at: www.ibrance.com/. Accessed November 14, 2017.
2. Palbociclib. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at www.NCCN.org. Accessed November 14, 2017.
3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2017. Available at: http://www.clinicalpharmacology-ip.com/.

4. National Comprehensive Cancer Network. Breast Cancer Version 3.2017. Available at https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf Accessed November 14, 2016.
5. National Comprehensive Cancer Network. Soft Tissue Sarcoma Version 1.2018. Available at https://www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf. Accessed November 14, 2016.
6. Dickson MA, Tap WD, Keohan ML, et al. Phase II trial of the CDK4 inhibitor PD0332991 in patients with advanced CDK4-amplified well differentiated or dedifferentiated liposarcoma. J Clin Oncol 2013;31(16):2024-2028.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	09.15	09.15
Policy converted to new template. New NCCN indication added (section I.A.3.b). ER positive changed to HR positive per PI, but ER and/or PR clarification added per UptoDate. Parenthetical drug classifications added for letrozole and fulvestrant from Lexicomp for clarity. Pregnancy removed as a contraindication. NCCN compendial recommendations closely follow the FDA approved indications; criteria was extended to men. All NCCN compendial recommendations, in addition to breast cancer, are added under Section I.B. Initial approval duration increased to 6 months.	07.16	08.16
Modified requirement related to initial endocrine-based therapy in combination with letrozole to allow use in combination with any aromatase inhibitor per PI; modified continued approval duration from 6 to 12 months; updated references.	04.17	06.17
1Q18 annual review: Converted to new template Added prescriber specialty requirement; Added max dosing criteria; Added criteria for off-label use for soft tissue sarcoma. References reviewed and updated.	11.17	02.18

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical

practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.