

## Ibrance<sup>®</sup> (palbociclib) (Oral)

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### I. Length of Authorization

Coverage is provided for 6 months and may be renewed.

### II. Dosing Limits

#### A. Quantity Limit (max daily dose) [NDC Unit]:

- All strengths: 21 tablets every 28 days

#### B. Max Units (per dose and over time) [HCPCS Unit]:

##### Breast Cancer

- 125 mg daily for 21 days out of every 28 days

##### STS - Liposarcoma

- 200 mg daily for 14 days out of every 21 days

### III. Initial Approval Criteria <sup>1</sup>

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**

#### Universal Criteria <sup>1</sup>

- Patient has not received previous therapy with a cyclin-dependent kinase (CDK) 4 and 6 inhibitor (e.g., ribociclib, abemaciclib, etc.); **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.); **AND**
  - Coadministration with strong CYP3A inhibitors (e.g., itraconazole, clarithromycin, nefazodone, grapefruit, grapefruit juice, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**

## Breast Cancer †<sup>1-5,9</sup>

- Patient has hormone receptor (HR)-positive disease; **AND**
- Patient has human epidermal growth factor receptor 2 (HER2)-negative disease; **AND**
- Used for recurrent unresectable (local or regional), advanced, or metastatic disease; **AND**
- Patient does not have visceral crisis; **AND**
- Patient is postmenopausal, premenopausal with ovarian ablation/suppression, or male with suppression of testicular steroidogenesis; **AND**
  - Used as initial therapy in combination with a non-steroidal aromatase inhibitor (i.e., anastrozole, letrozole, etc.) or fulvestrant; **OR**
  - Used as subsequent therapy in combination with fulvestrant

## Soft Tissue Sarcoma ‡<sup>4,6,7</sup>

- Patient has unresectable well-differentiated/dedifferentiated liposarcoma (WD-DDLS) of the retroperitoneum; **AND**
- Used as single agent therapy

† FDA Approved Indication(s); ‡ Compendia recommended indication(s); **Φ** Orphan Drug

## IV. Renewal Criteria<sup>1-7,9</sup>

Coverage can be renewed based upon the following criteria:

- Patient continues to meet universal and other indication-specific relevant criteria identified in section III; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: neutropenia, severe interstitial lung disease/pneumonitis, etc.

## V. Dosage/Administration<sup>1,7</sup>

| Indication          | Dose  |
|---------------------|---|
| Breast Cancer       | Administer 125 mg by mouth once daily for 21 consecutive days followed by 7 days off treatment per 28 day cycle. <ul style="list-style-type: none"><li>• Co-administer with an aromatase inhibitor or fulvestrant (<i>refer to the full prescribing information for the recommended doses</i>).</li></ul> |
| Soft Tissue Sarcoma | Administer 200 mg by mouth once daily for 14 consecutive days in a 21-day cycle   |

## VI. Billing Code/Availability Information

### HCP/PCS Code:

- J8999 – Prescription drug, oral, chemotherapeutic, Not Otherwise Specified
- C9399 – Unclassified drugs or biologicals

### NDC:

- Ibrance 125 mg tablet: 00069-0688- xx
- Ibrance 100 mg tablet: 00069-0486- xx
- Ibrance 75 mg tablet: 00069-0284- xx
- Ibrance 125 mg capsule: 00069-0189- xx
- Ibrance 100 mg capsule: 00069-0188- xx
- Ibrance 75 mg capsule: 00069-0187- xx

## VII. References

1. Ibrance [package insert]. New York, NY; Pfizer; November 2019. Accessed June 2022.
2. Cristofanilli M, Turner NC, Bondarenko I, et al. Fulvestrant plus palbociclib versus fulvestrant plus placebo for treatment of hormone-receptor-positive, HER2-negative metastatic breast cancer that progressed on previous endocrine therapy (PALOMA-3): final analysis of the multicentre, double-blind, phase 3 randomised controlled trial. *Lancet Oncol.* 2016 Apr;17(4):425-439. doi: 10.1016/S1470-2045(15)00613-0.
3. Finn RS, Martin M, Rugo HS, et al. Palbociclib and letrozole in advanced breast cancer. *N Engl J Med.* 2016;375(20):1925-1936.
4. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for palbociclib. National Comprehensive Cancer Network, 2022. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed June 2022.
5. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Breast Cancer 4.2022. National Comprehensive Cancer Network, 2022. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed July 2022.
6. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Soft Tissue Sarcoma 2.2022. National Comprehensive Cancer Network, 2022. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer

Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed June 2022.

7. 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 Jun 1;31(16):2024-8. doi: 10.1200/JCO.2012.46.5476.
8. Rugo HS, Diéras V, Gelmon KA, et al. Impact of palbociclib plus letrozole on patient-reported health-related quality of life: results from the PALOMA-2 trial. *Ann Oncol.* 2018 Apr 1;29(4):888-894. doi: 10.1093/annonc/mdy012.
9. Turner NC, Ro J, André F, et al; PALOMA3 Study Group. Palbociclib in Hormone-Receptor-Positive Advanced Breast Cancer. *N Engl J Med.* 2015 Jul 16;373(3):209-19. doi: 10.1056/NEJMoa1505270. Epub 2015 Jun 1.

## Appendix 1 – Covered Diagnosis Codes

| ICD-10  | Description   |
|---------|---|
| C48.0   | Malignant neoplasm of retroperitoneum                                     |
| C48.1   | Malignant neoplasm of specified parts of peritoneum                       |
| C48.2   | Malignant neoplasm of peritoneum, unspecified                             |
| C48.8   | Malignant neoplasm of overlapping sites of retroperitoneum and peritoneum |
| C49.4   | Malignant neoplasm of connective and soft tissue of abdomen               |
| C49.5   | Malignant neoplasm of connective and soft tissue of pelvis                |
| C49.8   | Malignant neoplasm of overlapping sites of connective and soft tissue     |
| C49.9   | Malignant neoplasm of connective and soft tissue, unspecified             |
| C50.011 | Malignant neoplasm of nipple and areola, right female breast              |
| C50.012 | Malignant neoplasm of nipple and areola, left female breast               |
| C50.019 | Malignant neoplasm of nipple and areola, unspecified female breast        |
| C50.021 | Malignant neoplasm of nipple and areola, right male breast                |
| C50.022 | Malignant neoplasm of nipple and areola, left male breast                 |
| C50.029 | Malignant neoplasm of nipple and areola, unspecified male breast          |
| C50.111 | Malignant neoplasm of central portion of right female breast              |
| C50.112 | Malignant neoplasm of central portion of left female breast               |
| C50.119 | Malignant neoplasm of central portion of unspecified female breast        |
| C50.121 | Malignant neoplasm of central portion of right male breast                |
| C50.122 | Malignant neoplasm of central portion of left male breast                 |
| C50.129 | Malignant neoplasm of central portion of unspecified male breast          |
| C50.211 | Malignant neoplasm of upper-inner quadrant of right female breast         |

|         |   |
|---------|---|
| C50.212 | Malignant neoplasm of upper-inner quadrant of left female breast        |
| C50.219 | Malignant neoplasm of upper-inner quadrant of unspecified female breast |
| C50.221 | Malignant neoplasm of upper-inner quadrant of right male breast         |
| C50.222 | Malignant neoplasm of upper-inner quadrant of left male breast          |
| C50.229 | Malignant neoplasm of upper-inner quadrant of unspecified male breast   |
| C50.311 | Malignant neoplasm of lower-inner quadrant of right female breast       |
| C50.312 | Malignant neoplasm of lower-inner quadrant of left female breast        |
| C50.319 | Malignant neoplasm of lower-inner quadrant of unspecified female breast |
| C50.321 | Malignant neoplasm of lower-inner quadrant of right male breast         |
| C50.322 | Malignant neoplasm of lower-inner quadrant of left male breast          |
| C50.329 | Malignant neoplasm of lower-inner quadrant of unspecified male breast   |
| C50.411 | Malignant neoplasm of upper-outer quadrant of right female breast       |
| C50.412 | Malignant neoplasm of upper-outer quadrant of left female breast        |
| C50.419 | Malignant neoplasm of upper-outer quadrant of unspecified female breast |
| C50.421 | Malignant neoplasm of upper-outer quadrant of right male breast         |
| C50.422 | Malignant neoplasm of upper-outer quadrant of left male breast          |
| C50.429 | Malignant neoplasm of upper-outer quadrant of unspecified male breast   |
| C50.511 | Malignant neoplasm of lower-outer quadrant of right female breast       |
| C50.512 | Malignant neoplasm of lower-outer quadrant of left female breast        |
| C50.519 | Malignant neoplasm of lower-outer quadrant of unspecified female breast |
| C50.521 | Malignant neoplasm of lower-outer quadrant of right male breast         |
| C50.522 | Malignant neoplasm of lower-outer quadrant of left male breast          |
| C50.529 | Malignant neoplasm of lower-outer quadrant of unspecified male breast   |
| C50.611 | Malignant neoplasm of axillary tail of right female breast              |
| C50.612 | Malignant neoplasm of axillary tail of left female breast               |
| C50.619 | Malignant neoplasm of axillary tail of unspecified female breast        |
| C50.621 | Malignant neoplasm of axillary tail of right male breast                |
| C50.622 | Malignant neoplasm of axillary tail of left male breast                 |
| C50.629 | Malignant neoplasm of axillary tail of unspecified male breast          |
| C50.811 | Malignant neoplasm of overlapping sites of right female breast          |
| C50.812 | Malignant neoplasm of overlapping sites of left female breast           |
| C50.819 | Malignant neoplasm of overlapping sites of unspecified female breast    |
| C50.821 | Malignant neoplasm of overlapping sites of right male breast            |

|         |   |
|---------|---|
| C50.822 | Malignant neoplasm of overlapping sites of left male breast         |
| C50.829 | Malignant neoplasm of overlapping sites of unspecified male breast  |
| C50.911 | Malignant neoplasm of unspecified site of right female breast       |
| C50.912 | Malignant neoplasm of unspecified site of left female breast        |
| C50.919 | Malignant neoplasm of unspecified site of unspecified female breast |
| C50.921 | Malignant neoplasm of breast (male)                                 |
| C50.922 | Malignant neoplasm of breast (male)                                 |
| C50.929 | Malignant neoplasm of breast (male)                                 |

## Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

| Medicare Part B Administrative Contractor (MAC) Jurisdictions |   |   |
|---|---|---|
| Jurisdiction  | Applicable State/US Territory   | Contractor  |
| E (1)   | CA, HI, NV, AS, GU, CNMI  | Noridian Healthcare Solutions, LLC                |
| F (2 & 3)   | AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ  | Noridian Healthcare Solutions, LLC                |
| 5   | KS, NE, IA, MO  | Wisconsin Physicians Service Insurance Corp (WPS) |
| 6   | MN, WI, IL  | National Government Services, Inc. (NGS)          |
| H (4 & 7)   | LA, AR, MS, TX, OK, CO, NM  | Novitas Solutions, Inc.                           |
| 8   | MI, IN  | Wisconsin Physicians Service Insurance Corp (WPS) |
| N (9)   | FL, PR, VI  | First Coast Service Options, Inc.                 |
| J (10)  | TN, GA, AL  | Palmetto GBA, LLC                                 |
| M (11)  | NC, SC, WV, VA (excluding below)  | Palmetto GBA, LLC                                 |
| L (12)  | DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA) | Novitas Solutions, Inc.                           |
| K (13 & 14)   | NY, CT, MA, RI, VT, ME, NH  | National Government Services, Inc. (NGS)          |
| 15  | KY, OH  | CGS Administrators, LLC                           |