IBRANCE® (palbociclib) Diagnosis Code Selection

IBRANCE 125 mg capsules and tablets are indicated for the treatment of adult patients with hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2-) advanced or metastatic breast cancer (mBC) in combination with:
- an aromatase inhibitor as initial endocrine-based therapy, or
- fulvestrant in patients with disease progression following endocrine therapy

ICD-10-CM

ICD-10-CM is a statistical classification system created by the U.S. Centers for Disease Control and Prevention for classifying diagnoses and reason for visits in all healthcare settings.

ICD-10-CM codes may include, but are not limited to, the following codes listed below. Reporting the medical necessity for IBRANCE may require a primary as well as secondary diagnosis, in some cases.

Female ICD-10-CM Codes[1]

	CODE	DESCRIPTION
FEMALE	C50.011	Malignant neoplasm of nipple and areola, right female breast
	C50.012	Malignant neoplasm of nipple and areola, left female breast
	C50.111	Malignant neoplasm of central portion, right female breast
	C50.112	Malignant neoplasm of central portion, left female breast
	C50.211	Malignant neoplasm of upper-inner quadrant, right female breast
	C50.212	Malignant neoplasm of upper-inner quadrant, left female breast
	C50.311	Malignant neoplasm of lower-inner quadrant, right female breast
	C50.312	Malignant neoplasm of lower-inner quadrant, left female breast
	C50.411	Malignant neoplasm of upper-outer quadrant, right female breast
	C50.412	Malignant neoplasm of upper-outer quadrant, left female breast
	C50.511	Malignant neoplasm of lower-outer quadrant, right female breast
	C50.512	Malignant neoplasm of lower-outer quadrant, left female breast
	C50.611	Malignant neoplasm of axillary tail, right female breast
	C50.612	Malignant neoplasm of axillary tail, left female breast
	C50.811	Malignant neoplasm of overlapping sites, right female breast
	C50.812	Malignant neoplasm of overlapping sites, left female breast
	C50.911	Malignant neoplasm of unspecified site, right female breast
	C50.912	Malignant neoplasm of unspecified site, left female breast
	D05.01	Lobular carcinoma in situ, right breast
	D05.02	Lobular carcinoma in situ, left breast
	D05.11	Intraductal carcinoma in situ, right breast
	D05.12	Intraductal carcinoma in situ, left breast
	D05.81	Other specified type of carcinoma in situ, right breast
	D05.82	Other specified type of carcinoma in situ, left breast

Please see the next page for the male ICD-10-CM codes.

Reference:
1. CMS, 2024 ICD-10-CM tabular list of disease and injuries, https://www.cms.gov/medicare/coding-billing/icd-10-codes/2024-icd-10-cm, Accessed April 4, 2024.

Please see additional Important Safety Information on page 3.

Please see full Prescribing Information for IBRANCE (palbociclib) 125 mg capsules and tablets.

For more information, please visit ibrance.pfizerpro.com.

IBRANCE® palbociclib

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Male ICD-10-CM Codes[1]

	CODE	DESCRIPTION
MALE	C50.021	Malignant neoplasm of nipple and areola, right male breast
	C50.022	Malignant neoplasm of nipple and areola, left male breast
	C50.121	Malignant neoplasm of central portion, right male breast
	C50.122	Malignant neoplasm of central portion, left male breast
	C50.221	Malignant neoplasm of upper-inner quadrant, right male breast
	C50.222	Malignant neoplasm of upper-inner quadrant, left male breast
	C50.321	Malignant neoplasm of lower-inner quadrant, right male breast
	C50.322	Malignant neoplasm of lower-inner quadrant, left male breast
	C50.421	Malignant neoplasm of upper-outer quadrant, right male breast
	C50.422	Malignant neoplasm of upper-outer quadrant, left male breast
	C50.521	Malignant neoplasm of lower-outer quadrant, right male breast
	C50.522	Malignant neoplasm of lower-outer quadrant, left male breast
	C50.621	Malignant neoplasm of axillary tail, right male breast
	C50.622	Malignant neoplasm of axillary tail, left male breast
	C50.821	Malignant neoplasm of overlapping sites, right male breast
	C50.822	Malignant neoplasm of overlapping sites, left male breast
	C50.921	Malignant neoplasm of unspecified site, right male breast
	C50.922	Malignant neoplasm of unspecified site, left male breast
	D05.01	Lobular carcinoma in situ, right breast
	D05.02	Lobular carcinoma in situ, left breast
	D05.11	Intraductal carcinoma in situ, right breast
	D05.12	Intraductal carcinoma in situ, left breast
	D05.81	Other specified type of carcinoma in situ, right breast
	D05.82	Other specified type of carcinoma in situ, left breast

Reference:
1. CMS, 2024 ICD-10-CM tabular list of disease and injuries, https://www.cms.gov/medicare/coding-billing/icd-10-codes/2024-icd-10-cm, Accessed April 4, 2024.

IBRANCE® (palbociclib) Important Safety Information

Neutropenia was the most frequently reported adverse reaction in PALOMA-2 (80%) and PALOMA-3 (83%). In PALOMA-2, Grade 3 (56%) or 4 (10%) decreased neutrophil counts were reported in patients receiving IBRANCE plus letrozole. In PALOMA-3, Grade 3 (55%) or Grade 4 (11%) decreased neutrophil counts were reported in patients receiving IBRANCE plus fulvestrant. Febrile neutropenia has been reported in 1.8% of patients exposed to IBRANCE across PALOMA-2 and PALOMA-3. One death due to neutropenic sepsis was observed in PALOMA-3. Inform patients to promptly report any fever.

Monitor complete blood count prior to starting IBRANCE, at the beginning of each cycle, on Day 15 of first 2 cycles and as clinically indicated. Dose interruption, dose reduction, or delay in starting treatment cycles is recommended for patients who develop Grade 3 or 4 neutropenia.

Severe, life-threatening, or fatal **interstitial lung disease (ILD) and/or pneumonitis** can occur in patients treated with CDK4/6 inhibitors, including IBRANCE when taken in combination with endocrine therapy. Across clinical trials (PALOMA-1, PALOMA-2, PALOMA-3), 1.0% of IBRANCE-treated patients had ILD/pneumonitis of any grade, 0.1% had Grade 3 or 4, and no fatal cases were reported. Additional cases of ILD/pneumonitis have been observed in the post-marketing setting, with fatalities reported.

Monitor patients for pulmonary symptoms indicative of ILD/pneumonitis (e.g., hypoxia, cough, dyspnea). In patients who have new or worsening respiratory symptoms and are suspected to have developed pneumonitis, interrupt IBRANCE immediately and evaluate the patient. Permanently discontinue IBRANCE in patients with severe ILD or pneumonitis.

Based on the mechanism of action, IBRANCE can cause **fetal harm**. Advise females of reproductive potential to use effective contraception during IBRANCE treatment and for at least 3 weeks after the last dose. IBRANCE may **impair fertility in males** and has the potential to cause genotoxicity. Advise male patients to consider sperm preservation before taking IBRANCE. Advise male patients with female partners of reproductive potential to use effective contraception during IBRANCE treatment and for 3 months after the last dose. Advise females to inform their healthcare provider of a known or suspected pregnancy. Advise women **not to breastfeed** during IBRANCE treatment and for 3 weeks after the last dose because of the potential for serious adverse reactions in nursing infants.

The **most common adverse reactions (≥10%)** of any grade reported in **PALOMA-2** for IBRANCE plus letrozole vs placebo plus letrozole were neutropenia (80% vs 6%), infections (60% vs 42%), leukopenia (39% vs 2%), fatigue (37% vs 28%), nausea (35% vs 26%), alopecia (33% vs 16%), stomatitis (30% vs 14%), diarrhea (26% vs 19%), anemia (24% vs 9%), rash (18% vs 12%), asthenia (17% vs 12%), thrombocytopenia (16% vs 1%), vomiting (16% vs 17%), decreased appetite (15% vs 9%), dry skin (12% vs 6%), pyrexia (12% vs 9%), and dysgeusia (10% vs 5%).

The **most frequently reported Grade ≥3 adverse reactions (≥5%)** in **PALOMA-2** for IBRANCE plus letrozole vs placebo plus letrozole were neutropenia (66% vs 2%), leukopenia (25% vs 0%), infections (7% vs 3%), and anemia (5% vs 2%).

Lab abnormalities of any grade occurring in **PALOMA-2** for IBRANCE plus letrozole vs placebo plus letrozole were decreased WBC (97% vs 25%), decreased neutrophils (95% vs 20%), anemia (78% vs 42%), decreased platelets (63% vs 14%), increased aspartate aminotransferase (52% vs 34%), and increased alanine aminotransferase (43% vs 30%).

The **most common adverse reactions (≥10%)** of any grade reported in **PALOMA-3** for IBRANCE plus fulvestrant vs placebo plus fulvestrant were neutropenia (83% vs 4%), leukopenia (53% vs 5%), infections (47% vs 31%), fatigue (41% vs 29%), nausea (34% vs 28%), anemia (30% vs 13%), stomatitis (28% vs 13%), diarrhea (24% vs 19%), thrombocytopenia (23% vs 0%), vomiting (19% vs 15%), alopecia (18% vs 6%), rash (17% vs 6%), decreased appetite (16% vs 8%), and pyrexia (13% vs 5%).

The **most frequently reported Grade ≥3 adverse reactions (≥5%)** in **PALOMA-3** for IBRANCE plus fulvestrant vs placebo plus fulvestrant were neutropenia (66% vs 1%) and leukopenia (31% vs 2%).

Lab abnormalities of any grade occurring in **PALOMA-3** for IBRANCE plus fulvestrant vs placebo plus fulvestrant were decreased WBC (99% vs 26%), decreased neutrophils (96% vs 14%), anemia (78% vs 40%), decreased platelets (62% vs 10%), increased aspartate aminotransferase (43% vs 48%), and increased alanine aminotransferase (36% vs 34%).

Avoid concurrent use of **strong CYP3A inhibitors**. If patients must be administered a strong CYP3A inhibitor, reduce the IBRANCE dose to 75 mg. If the strong inhibitor is discontinued, increase the IBRANCE dose (after 3-5 half-lives of the inhibitor) to the dose used prior to the initiation of the strong CYP3A inhibitor. Grapefruit or grapefruit juice may increase plasma concentrations of IBRANCE and should be avoided. Avoid concomitant use of **strong CYP3A inducers**. The dose of **sensitive CYP3A substrates** with a narrow therapeutic index may need to be reduced as IBRANCE may increase their exposure.

For patients with **severe hepatic impairment** (Child-Pugh class C), the recommended dose of IBRANCE is 75 mg. The pharmacokinetics of IBRANCE **have not been studied** in patients **requiring hemodialysis.**

IBRANCE® palbociclib

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