



PRIOR AUTHORIZATION POLICY

- POLICY:** Oncology (Oral – Cyclin-Dependent Kinase 4 and 6 Inhibitor) – Ibrance Prior Authorization Policy
- Ibrance® (palbociclib capsules and tablets – Pfizer)

REVIEW DATE: 02/18/2026

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Ibrance, a cyclin-dependent kinase (CDK) 4/6 inhibitor, is indicated for the treatment of hormone receptor positive (HR+), human epidermal growth factor receptor 2 (HER2)-negative **breast cancer** in adults, in combination with:¹

- An aromatase inhibitor (AI) as initial endocrine-based therapy for advanced or metastatic disease.
- Fulvestrant in patients with disease progression following endocrine therapy for advanced or metastatic disease.
- Itovebi™ (inavolisib tablets) and fulvestrant for endocrine-resistant, phosphatidylinositol-3-kinase (PIK3CA)-mutated, locally advanced or metastatic disease, as detected by an FDA-approved test, following recurrence on or after completing adjuvant endocrine therapy.

Guidelines

Ibrance is discussed in guidelines from the National Comprehensive Cancer Network (NCCN):

- **Breast Cancer:** NCCN guidelines (version 1.2026 – January 16, 2026) recommend Ibrance + AI or fulvestrant (category 2A) as a first-line “Preferred Regimen” for recurrent unresectable (local or regional) or Stage IV HR+ and HER2-negative disease.^{2,3} CDK4/6 inhibitor + fulvestrant is recommended for second- and subsequent-line therapy as a “Preferred Regimen”, if CDK4/6 inhibitor was not previously used (category 1). Ibrance is also recommended as first-line therapy in combination with Itovebi and fulvestrant for *PIK3CA* activating mutation after disease progression on adjuvant endocrine therapy or early disease relapse within 12 months of adjuvant endocrine therapy completion as “Useful in Certain Circumstances” (category 1). Ibrance is also recommended in combination with an aromatase inhibitor, trastuzumab, and Perjeta® (pertuzumab intravenous infusion) for recurrent unresectable (local or regional) or Stage IV HR+, HER+ disease (category 2A). The recommendations above are for postmenopausal women or premenopausal patients receiving ovarian ablation or suppression. The compendium recommends that men with breast cancer be treated similarly to postmenopausal women, except that the use of an AI is ineffective without concomitant suppression of testicular steroidogenesis.³
- **Endometrial Carcinoma:** NCCN uterine neoplasm guidelines (version 2.2026 – November 14, 2025) recommend Ibrance in combination with letrozole for estrogen receptor (ER) positive endometrial carcinoma as primary treatment for disease that is not suitable for surgery (category 2A/2B) or for recurrent or metastatic disease as “Useful in Certain Circumstances” (category 2A).^{3,4}
- **Liposarcoma:** NCCN guidelines on soft tissue sarcoma (version 1.2026 – January 16, 2026) recommend Ibrance as a single agent for the treatment of unresectable well-differentiated or dedifferentiated liposarcoma as “Useful in Certain Circumstances” (category 2A).^{3,5}
- **Uterine Sarcoma:** NCCN uterine neoplasm guidelines (version 2.2026 – November 14, 2025) recommend Ibrance as second-line or subsequent therapy for advanced, recurrent/metastatic, or inoperable disease with *CDK4* amplification (category 2A).^{3,4}

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Ibrance. All approvals are provided for the duration noted below. In the clinical criteria, as appropriate, an asterisk (*) is noted next to the specified gender. In this context, the specified gender is defined as follows: a woman is defined as an individual with the biological traits of a woman, regardless of the individual’s gender identity or gender expression; men are defined as individuals with the biological traits of a man, regardless of the individual’s gender identity or gender expression.

- **Ibrance® (palbociclib capsules and tablets (Pfizer)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indications

- 1. Breast Cancer in a Woman*.** Approve for 1 year if the patient meets ALL of the following (A, B, C, D, E, and F):
 - A)** Patient is \geq 18 years of age; AND
 - B)** Patient has recurrent or metastatic disease; AND

- C)** Patient has hormone receptor positive (HR+) [i.e., estrogen receptor positive {ER+} and/or progesterone receptor positive {PR+}] disease; AND
- D)** Patient meets ONE of the following (i or ii):
 - i.** Patient has human epidermal growth factor receptor 2 (HER2)-negative breast cancer; OR
 - ii.** Patient meets BOTH of the following (a and b):
 - a)** Patient has human epidermal growth factor receptor 2 (HER2)-positive breast cancer; AND
 - b)** The medication will be used in combination with an aromatase inhibitor, trastuzumab, and Perjeta (pertuzumab intravenous infusion); AND
- E)** Patient meets ONE of the following (i or ii):
 - i.** Patient is postmenopausal; OR
 - ii.** Patient is pre/perimenopausal and meets ONE of the following (a or b):
 - a)** Patient is receiving ovarian suppression/ablation with a gonadotropin-releasing hormone (GnRH) agonist; OR
Note: Examples of a GnRH agonist include leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous injection).
 - b)** Patient has had surgical bilateral oophorectomy or ovarian irradiation; AND
- F)** Patient meets ONE of the following (i or ii):
 - i.** Ibrance will be used in combination with anastrozole, exemestane, or letrozole; OR
 - ii.** Ibrance will be used in combination with fulvestrant.

* Refer to the Policy Statement.

- 2. Breast Cancer in a Man*.** Approve for 1 year if the patient meets ALL of the following (A, B, C, D, and E):
- A)** Patient is ≥ 18 years of age; AND
 - B)** Patient has recurrent or metastatic disease; AND
 - C)** Patient has hormone receptor positive (HR+) [i.e., estrogen receptor positive {ER+} and/or progesterone receptor positive {PR+}] disease; AND
 - D)** Patient meets ONE of the following (i or ii):
 - i.** Patient has human epidermal growth factor receptor 2 (HER2)-negative breast cancer; OR
 - ii.** Patient meets BOTH of the following (a and b):
 - a)** Patient has human epidermal growth factor receptor 2 (HER2)-positive breast cancer; AND
 - b)** The medication will be used in combination with an aromatase inhibitor, trastuzumab, and Perjeta (pertuzumab intravenous infusion); AND
 - E)** Patient meets ONE of the following (i or ii):
 - i.** Patient meets BOTH of the following (a and b):
 - a)** Patient is receiving a gonadotropin-releasing hormone (GnRH) analog; AND
Note: Examples of a GnRH analog include leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), Firmagon (degarelix acetate subcutaneous injection), Orgovyx (relugolix tablet).
 - b)** Ibrance will be used in combination with anastrozole, exemestane, or letrozole; OR
 - ii.** Ibrance will be used in combination with fulvestrant.

* Refer to the Policy Statement.

Other Uses with Supportive Evidence

3. Endometrial Cancer. Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):

- A)** Patient is \geq 18 years of age; AND
- B)** Patient has estrogen receptor (ER)-positive tumors; AND
- C)** Patient meets ONE of the following (i or ii):
 - i.** According to the prescriber, the patient is not a candidate for surgery; OR
 - ii.** Patient has recurrent or metastatic disease; AND
- D)** The medication will be used in combination with letrozole.

4. Liposarcoma. Approve for 1 year if the patient meets BOTH of the following (A and B):

- A)** Patient is \geq 18 years of age; AND
- B)** Patient has well-differentiated or dedifferentiated liposarcoma.

5. Uterine Sarcoma. Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):

- A)** Patient is \geq 18 years of age; AND
 - B)** Patient has advanced, recurrent, metastatic, or inoperable disease; AND
 - C)** Patient has *CDK4* amplified disease; AND
 - D)** Patient has tried at least one systemic regimen; AND
- Note: Examples of a systemic regimen include one or more of the following agents: dacarbazine, docetaxel, doxorubicin, gemcitabine, ifosfamide, or Yondelis (trabectedin intravenous infusion).

CONDITIONS NOT COVERED

- **Ibrance® (palbociclib capsules and tablets (Pfizer)**

is(are) considered not medically necessary for ANY other use(s).

REFERENCES

1. Ibrance® capsules and tablets [prescribing information]. New York, NY: Pfizer; April 2025.
2. The NCCN Breast Cancer Clinical Practice Guidelines in Oncology (version 1.2026 – January 16, 2026). © 2026 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on February 16, 2026.
3. The NCCN Drugs & Biologics Compendium. © 2026 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on February 16, 2026. Search terms: palbociclib.
4. The NCCN Uterine Neoplasms Clinical Practice Guidelines in Oncology (version 2.2026 – November 14, 2025). © 2025 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on February 16, 2026.
5. The NCCN Soft Tissue Sarcoma Clinical Practice Guidelines in Oncology (version 1.2026 – January 16, 2026) © 2026 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on February 16, 2026.

HISTORY

Type of Revision	Summary of Changes	Review Date
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Annual Revision	No criteria changes.	02/21/2024
Annual Revision	No criteria changes.	02/26/2025
Update	04/21/2025: The policy name was changed from "Oncology – Ibrance PA Policy" to "Oncology (Oral - Cyclin-Dependent Kinase 4 and 6 Inhibitor) – Ibrance PA Policy".	N/A
Update	5/1/2025: The overview section was updated to include new FDA approved indication for combination use with Itovebi™ (inavolisib tablets) and fulvestrant.	N/A
Annual Revision	<p>Breast Cancer in a Woman: An option for approval was added for a patient with human epidermal growth factor receptor 2 (HER2)-positive breast cancer when the medication is used in combination with an aromatase inhibitor, trastuzumab, and Perjeta (pertuzumab intravenous infusion).</p> <p>Breast Cancer in a Man: An option for approval was added for a patient with human epidermal growth factor receptor 2 (HER2)-positive breast cancer when the medication is used in combination with an aromatase inhibitor, trastuzumab, and Perjeta (pertuzumab intravenous infusion).</p> <p>Endometrial Cancer: Condition of approval and criteria were added to Other Uses with Supportive Evidence.</p> <p>Uterine Sarcoma: Condition of approval and criteria were added to Other Uses with Supportive Evidence.</p>	02/18/2026

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