DRUG QUANTITY MANAGEMENT POLICY – PER RX

POLICY: Oncology (Oral – Cyclin-Dependent Kinase 4/6 Inhibitor) – Ibrance Drug Quantity Management Policy – Per Rx
- Ibrance® (palbociclib capsules and tablets – Pfizer)

REVIEW DATE: 09/04/2025

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.

Dosing

The recommended dose of Ibrance is 125 mg once daily (QD) for 21 consecutive days followed by 7 days off treatment to comprise a complete cycle of 28 days.[1] It should be administered in combination with other agents.

To manage adverse events, dose reductions/modifications to 100 mg QD or 75 mg QD may be needed.[1] Similarly, dose reductions may be needed to manage drug interactions and hepatic impairment, as well as hematologic and non-hematologic toxicities.

Availability

Ibrance is available as 75 mg, 100 mg and 125 mg capsules and tablets.[1]

Off-Label Dosing

Guidelines also support the use of Ibrance for liposcaroma.[2,3] Ibrance doses of 125 mg QD for 21 days in a 28-day cycle as well as 200 mg QD for 14 consecutive days in a 21-day cycle have been studied for liposarcoma.[3,4]

POLICY STATEMENT

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of Ibrance. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for 1 year in duration.

Drug Quantity Limits

Product	Strength and Form	Retail Maximum Quantity per Rx	Home Delivery Maximum Quantity per Rx
Ibrance® (palbociclib capsules and tablets)	75 mg capsules and tablets	21 capsules/tablets	63 capsules/tablets
	100 mg capsules and tablets	21 capsules/tablets	63 capsules/tablets
	125 mg capsules and tablets	21 capsules/tablets	63 capsules/tablets

EXCEPTIONS TO THE QUANTITY LIMITS LISTED ABOVE ARE COVERED AS MEDICALLY NECESSARY WHEN THE FOLLOWING CRITERIA ARE MET. ANY OTHER EXCEPTION IS CONSIDERED NOT MEDICALLY NECESSARY.

CRITERIA

Ibrance 75 mg capsules and tablets
No overrides recommended.

Ibrance 100 mg capsules and tablets

1. If the patient has liposarcoma, approve 28 capsules or tablets per dispensing at retail or 84 capsules or tablets per dispensing at home delivery.

Ibrance 125 mg capsules and tablets
No overrides recommended.

REFERENCES

1. Ibrance® capsules and tablets [prescribing information]. New York, NY: Pfizer Labs; April 2025.
2. The NCCN Soft Tissue Sarcoma Clinical Practice Guidelines in Oncology (version 1.2025 – May 2, 2025) © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on August 11, 2025.
3. 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.
4. Dickson MA, Schwartz GK, Keohan ML, et al. Progression-free survival among patients with well-differentiated or dedifferentiated liposarcoma treated with CDK inhibitor palbociclib: a phase 2 clinical trial. 2016;2(7):937-940.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	New policy created to provide overrides to previously existing quantity limits.	09/11/2024
Annual Revision	The title of the policy was changed from "Oncology – Ibrance Drug Quantity Management Policy – Per Rx" to "Oncology (Oral – Cyclin-Dependent Kinase 4/6 Inhibitor) – Ibrance Drug Quantity Management Policy – Per Rx"	09/04/2025