

Clinical Policy Title:	Cyclin Dependent Kinases (CDK) Inhibitors
Policy Number:	RxA.163
Drug(s) Applied:	Ibrance (palbociclib), Kisqali (ribociclib), Verzenio (abemaciclib), Truqap (capivasertib), Piqray (alpelisib)
Original Policy Date:	02/07/2020
Last Review Date:	12/11/2025
Line of Business Policy Applies to:	All lines of Business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Breast Cancer (must meet all):

1. Diagnosis of breast cancer;
2. Disease is HR-positive and HER2-negative;
3. Diagnosis is an FDA-approved indication as outlined in Appendix A.

Approval Duration

All Lines of Business (except Medicare): 12 months, Split-Fill (Truqap and Verzenio only)

II. Continued Therapy Approval

A. Breast Cancer (must meet all):

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

Approval Duration All Lines of Business (except Medicare): 12 months

Appendix A.

Medication	FDA-Approved Indications
Ibrance	<ol style="list-style-type: none"> 1. Advanced or metastatic breast cancer in combination with an aromatase inhibitor as initial endocrine-based therapy or with fulvestrant in patients with disease progression following endocrine therapy. 2. Endocrine-resistant, PIK3CA-mutated, locally advanced or metastatic breast cancer in combination with inavolsib and fulvestrant, following recurrence on or after completing adjuvant endocrine therapy.
Kisqali	<ol style="list-style-type: none"> 1. Stage II or III early breast cancer at risk for recurrence in combination with an aromatase inhibitor for adjuvant treatment. 2. Advanced or metastatic breast cancer in combination with an aromatase inhibitor as initial endocrine-based therapy or with fulvestrant as initial endocrine-based therapy or following disease progression on endocrine therapy.
Piqray	<ol style="list-style-type: none"> 1. Advanced breast cancer with a PIK3CA mutation in combination with fulvestrant after disease progression on an endocrine-based regimen.

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

Truqap	1. Locally advanced or metastatic breast cancer with one or more PIK3CAAKT1/PTEN-alternations in combination with fulvestrant following progression on at least one endocrine-based regimen in the metastatic setting or recurrent on or within 12 months of completing adjuvant therapy.
Verzenio	<ol style="list-style-type: none"> 1. Early breast cancer at high risk of recurrence in combination with tamoxifen or an aromatase inhibitor for adjuvant treatment. 2. Advanced or metastatic breast cancer in combination with an aromatase inhibitor as initial endocrine-based therapy or with fulvestrant in patients with disease progression following endocrine therapy. 3. As monotherapy for advanced or metastatic breast cancer with disease progression following endocrine therapy and prior chemotherapy in the metastatic setting.

References

1. National Comprehensive Cancer Network. Breast Cancer Version 1.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed February 28, 2025.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	02/07/2020
Policy was reviewed: <ol style="list-style-type: none"> 1. Clinical Policy Title was updated. 2. Drug(s) Applied was updated. 3. Line of Business Policy Applies to was updated. 4. Continued Therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance..." 5. Initial and Continued Therapy Approval criteria: Commercial approval duration was updated. 6. Added "Disease has not progressed on prior CDK4/6 inhibitor therapy" to initial approval criteria for both indications; 7. References were updated. 	08/03/2020	09/14/2020
Policy was reviewed: <ol style="list-style-type: none"> 1. References were updated. 	03/31/2021	06/10/2021
Policy was reviewed: <ol style="list-style-type: none"> 1. Initial approval criteria I.A.6 and I.B.5 were updated to add examples of CDK 4/6 inhibitors as Verzenio, Kisqali. 	06/10/2021	12/07/2021
Policy was reviewed:	01/13/2022	04/18/2022

<ol style="list-style-type: none"> Continued Therapy Criteria II.A.3: Updated from If breast cancer, dose is ≥ 75 mg per day to If breast cancer, dose is ≥ 75 mg per day (If dose reduction below 75 mg is required, discontinue); References were reviewed and updated. 		
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> Initial Approval Criteria, I.A.6: Updated to include new criteria pertaining to indication Breast cancer, if member is a premenopausal female, member has been treated with ovarian ablation or is receiving ovarian suppression. Initial Approval Criteria, I.A.8 and I.B.7: Updated to include new concurrent therapy criteria Ibrance® is not prescribed concurrently with another CDK 4/6 inhibitor therapy (e.g., Verzenio®, Kisqali®). Continued Therapy Approval Criteria, II.A.3: Updated to include new concurrent therapy criteria Ibrance® is not prescribed concurrently with another CDK 4/6 inhibitor therapy (e.g., Verzenio®, Kisqali®). References were reviewed and updated. 	02/24/2023	04/13/2023
<p>Policy was reviewed.</p>	10/19/2023	10/19/2023
<p>Policy was reviewed.</p> <ol style="list-style-type: none"> Removed age criteria. Removed dose criteria. Removed criteria preventing concurrent prescribing. Updated approval duration. Removed reauthorization criteria for positive response to therapy. 	12/13/2023	11/30/2023
<p>Policy was reviewed.</p> <ol style="list-style-type: none"> Removed “if member is premenopausal...” criteria. Removed criteria related to disease progression on prior therapy. Updated approval duration. Removed soft tissue sarcoma (off label) indication. References were reviewed and updated. 	01/05/2024	01/01/2024
<p>Policy was reviewed</p> <ol style="list-style-type: none"> Merged with Verzenio <p>Relaxed criteria to ask for diagnosis only.</p>	3/1/2024	3/1/2024

<p>Policy was reviewed</p> <ol style="list-style-type: none"> 1. Policy updated to include new drug, Traqap™ & Piqray®. 2. Approval duration was updated. 3. Continuation criteria Updated. 4. References were reviewed and updated. 	6/14/2024	6/14/2024
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. References were reviewed and updated. 2. Package inserts were reviewed for new indications and updated accordingly. 3. Split fill applied to Truqap and Verzenio only. 	2/28/2025	3/18/2025
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Package inserts were reviewed for new indications and updated accordingly. 2. References were reviewed and updated. 	05/06/2025	05/05/2025
<p>Policy reviewed.</p>	12/11/2025	12/11/2025