Clinical Policy Title:	Cyclin Dependent Kinases (CDK) Inhibitors
Policy Number:	RxA.163
Drug(s) Applied:	Ibrance (palbociclib), Kisqali (ribociclib), Kisqali-Femara (ribociclib-letrozole) Co-Pack, Verzenio (abemaciclib), Truqap (capivasertib), Piqray (alpelisib)
Original Policy Date:	02/07/2020
Last Review Date:	06/14/2024
Line of Business Policy Applies to:	All lines of Business (except Medicare)

Criteria

I. Initial Approval Criteria (ePA)

A. Breast Cancer (must meet all)**:**

1. Diagnosis of locally advanced or metastatic breast cancer;
2. For Ibrance® only, trial and failure, contraindication, or intolerance to both of the following (a and b):
   a. Kisqali® (ribociclib) or Kisqali-Femara (ribociclib-letrozole);
   b. Verzenio® (abemaciclib);
3. For Truqap™ and Piqray® only:
   a. Prescribed in combination with fulvestrant;
   b. Disease has all of the following characteristics (i, ii, and iii):
      i. Hormone receptor (HR)-positive;
      ii. Human epidermal growth factor receptor 2 (HER2)-negative;
      iii. PIK3CA/AKT1/PTEN-alterations for Truqap, or PIK3CA-alteration for Piqray;
   c. One of the following (i or ii):
      i. Disease has progressed on at least one endocrine-based regimen in the metastatic setting (e.g., anastrozole, letrozole, exemestane, tamoxifen, etc.);
      ii. Recurrence on or within 12 months of completing adjuvant therapy (e.g., chemotherapy).

Approval Duration

All Lines of Business (except Medicare): 12 months, Split-fill

II. Continued Therapy Approval (APA)

A. Breast Cancer:

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

References

1. National Comprehensive Cancer Network. Breast Cancer Version 2.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed June 14, 2024.
2. National Comprehensive Cancer Network. Soft Tissue Sarcoma Version 1.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf. Accessed June 14, 2024.

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. Available at: https://ascopubs.org/doi/10.1200/JCO.2012.46.5476. Accessed June 14, 2024.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	02/07/2020
Policy was reviewed: 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: 1. References were updated.	03/31/2021	06/10/2021
Policy was reviewed: 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: 1. 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); 2. References were reviewed and updated.	01/13/2022	04/18/2022
Policy was reviewed: 1. 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. 2. Initial Approval Criteria, I.A.8 and I.B.7:	02/24/2023	04/13/2023

Updated to include new concurrent therapy criteria Ibrance® is not prescribed concurrently with another CDK 4/6 inhibitor therapy (e.g., Verzenio®, Kisqali®). 3. 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®). 4. References were reviewed and updated.		
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed. 1. Removed age criteria. 2. Removed dose criteria. 3. Removed criteria preventing concurrent prescribing. 4. Updated approval duration. 5. Removed reauthorization criteria for positive response to therapy.	12/13/2023	11/30/2023
Policy was reviewed. 1. Removed "if member is premenopausal…" criteria. 2. Removed criteria related to disease progression on prior therapy. 3. Updated approval duration. 4. Removed soft tissue sarcoma (off label) indication. 5. References were reviewed and updated.	01/05/2024	01/01/2024
Policy was reviewed 1. Merged with Verzenio 2. Relaxed criteria to ask for diagnosis only.	3/1/2024	3/1/2024
Policy was reviewed 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