Reference number(s)
1639-A

Specialty Guideline Management
Kisqali

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Kisqali	ribociclib

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications[1]

Kisqali is indicated in combination with an aromatase inhibitor for the adjuvant treatment of adults with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative stage II and III early breast cancer at high risk of recurrence.

Kisqali is indicated for the treatment of adults with HR-positive, HER2-negative advanced or metastatic breast cancer in combination with:

- An aromatase inhibitor as initial endocrine-based therapy; or
- Fulvestrant as initial endocrine-based therapy or following disease progression on endocrine therapy.

Compendial Uses[2]

- Breast cancer

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- Endometrial carcinoma

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

- Documentation of laboratory results confirming hormone receptor (HR) and human epidermal growth factor receptor 2 (HER2) status.
- Documentation of laboratory results confirming estrogen receptor 1 (ESR1) status, where applicable.
- For members requesting initiation of therapy for the treatment of endometrial carcinoma: documentation of laboratory results confirming estrogen receptor (ER) status.

Coverage Criteria

Breast cancer[1-3]

Authorization of 12 months may be granted to members for treatment of HR-positive, HER2-negative breast cancer when one of the following criteria is met:

- Member has recurrent unresectable or metastatic disease and the requested medication is used in any of the following regimens:
    - The requested medication is used in combination with an aromatase inhibitor (e.g., anastrozole, exemestane, letrozole).
    - The requested medication is used in combination with fulvestrant.
- Member has ESR1-mutated locally advanced or metastatic disease and the requested medication with be used in combination with Etcamah (camizestrant).

Authorization of 12 months may be granted to members for adjuvant treatment of HR-positive, HER2-negative breast cancer when used in combination with an aromatase inhibitor (e.g., anastrozole, letrozole, exemestane) and either of the following criteria is met:

- Disease has any lymph node involvement (excluding microscopic nodal involvement).
- Disease has no nodal involvement and either of the following criteria is met:
    - Tumor size is greater than 5 cm.
    - Tumor size is 2 to 5 cm and the tumor is Grade 2 (and high genomic risk or Ki-67 greater than or equal to 20%) or Grade 3.

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Endometrial carcinoma[2]

Authorization of 12 months may be granted to members for treatment of recurrent or metastatic endometrial carcinoma with ER-positive tumors when used in combination with letrozole.

Authorization of 12 months may be granted to members for adjuvant treatment of stage IV endometrial carcinoma with ER-positive tumors when used in combination with letrozole.

Continuation of Therapy

Adjuvant Breast Cancer Treatment

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for adjuvant treatment of HR-positive, HER2-negative breast cancer until completion of 3 years of treatment or until disease recurrence or unacceptable toxicity while on the current regimen.

Recurrent Unresectable or Metastatic Breast Cancer or Endometrial Carcinoma

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for recurrent unresectable or metastatic breast cancer or endometrial carcinoma when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

References

1. Kisqali [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; September 2025.
2. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed November 13, 2025.
3. Etcamah [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; September 2026.

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