Reference number(s)
2104-A

Specialty Guideline Management
Kisqali Femara Co-Pack

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 Femara Co-Pack	ribociclib tablets; letrozole tablets

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 Femara Co-Pack is indicated 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 Femara Co-Pack is indicated as initial endocrine-based therapy for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer.

Compendial Uses[2]

- Breast cancer
- Endometrial carcinoma

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

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Documentation

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

- For members requesting initiation of therapy for the treatment of breast cancer: documentation of hormone receptor (HR) and human epidermal growth factor receptor 2 (HER2) status.
- 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[1,2]

Authorization of 12 months may be granted to members for the treatment of HR-positive, HER2-negative recurrent unresectable or metastatic breast cancer.

Authorization of 12 months may be granted to members for adjuvant treatment of HR-positive, HER2-negative breast cancer when 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.

Endometrial carcinoma[2]

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

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

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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 Femara Co-Pack [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.