Reference number(s)
1639-A

SPECIALTY GUIDELINE MANAGEMENT

KISQALI (ribociclib)

POLICY

I. 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.

A. FDA-Approved Indications
   1. Kisqali is indicated in combination with an aromatase inhibitor 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.

   2. Kisqali is indicated in combination with fulvestrant for the treatment of postmenopausal women or in men with (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer, as initial endocrine based therapy or following disease progression on endocrine therapy.

B. Compendial Uses
   1. Breast cancer
   2. Endometrial carcinoma

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

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:
A. For members requesting initiation of therapy for the treatment of breast cancer: documentation of laboratory results confirming hormone receptor (HR) and human epidermal growth factor receptor 2 (HER2) status
B. For members requesting initiation of therapy for the treatment of endometrial carcinoma: documentation of laboratory results confirming estrogen receptor (ER) status

III. CRITERIA FOR INITIAL APPROVAL

A. Breast cancer
Authorization of 12 months may be granted to members for treatment of HR-positive, HER2-negative recurrent, advanced, or metastatic breast cancer when used in combination with an aromatase inhibitor or fulvestrant.

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

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication outlined in section III when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

V. REFERENCES

1. Kisqali [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; August 2023.
2. The NCCN Drugs & Biologics Compendium® © 2023 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed October 24, 2023.