

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 pre/perimenopausal or postmenopausal women 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 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

Breast cancer: Recurrent HR-positive, HER2-negative disease.

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

II. DOCUMENTATION

Submission of hormone receptor (HR) and human epidermal growth factor receptor 2 (HER2) status is necessary to initiate the prior authorization review.

III. CRITERIA FOR INITIAL APPROVAL

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 Kisqali is used in combination with an aromatase inhibitor or fulvestrant.

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.

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V. REFERENCES

1. KISQALI [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2020.
2. The NCCN Drugs & Biologics Compendium® © 2020 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed November 27, 2020.