Reference number(s)
2104-A

SPECIALTY GUIDELINE MANAGEMENT

KISQALI FEMARA CO-PACK (ribociclib tablets; letrozole tablets)

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 Indication
The Kisqali Femara Co-Pack is indicated 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.

B. Compendial Uses
Breast cancer: Therapy for 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 the treatment of HR-positive, HER2-negative recurrent, advanced or metastatic breast cancer.

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 Femara Co-Pack [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2020.
2. Ribociclib. The NCCN Drugs & Biologics Compendium® © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed November 25, 2020.