# SPECIALTY GUIDELINE MANAGEMENT

## KISQALI (ribociclib) 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.

**FDA-Approved Indication** 

- 1. Kisqali is indicated in combination with an aromatase inhibitor as initial endocrine-based therapy for the treatment of 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.
- 3. The Kisqali Femara Co-Pack is indicated as initial endocrine-based therapy for the treatment of postmenopausal women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer.

All other indications are considered experimental/investigational and are not a covered benefit.

#### **II. CRITERIA FOR INITIAL APPROVAL**

#### **Breast cancer**

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

#### **III. CONTINUATION OF THERAPY**

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

#### **IV. REFERENCES**

1. Kisqali [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2018.

Kisqali, Kisqali Femara Co-Pack 2019

© 2018 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.

