Reference number(s)
1639-A

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.