Kisqali (ribociclib succinate)/ Kisqali-Femara Co-pack (ribociclib succinate/letrozole)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Kisqali (ribociclib succinate) tablets Kisqali Femara (ribociclib succinate/letrozole) co-pack	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Kisqali (ribociclib) may be approved if the following criteria are met:

I. Individual has a diagnosis of advanced, recurrent unresectable, or metastatic breast cancer; **AND**
II. Individual has hormone receptor-positive, human epidermal growth factor receptor 2-negative (HR+/ HER2-) breast cancer;
AND
III. Individual meets one of the following:
   A. Male; **OR**
   B. Postmenopausal female; **OR**
   C. Premenopausal treated with ovarian ablation/suppression;
AND
IV. Individual is using in one of the following ways:
   A. Individual is using as an initial endocrine-based therapy in combination with an aromatase inhibitor (Label, NCCN 1); **OR**
   B. Individual is using fulvestrant as initial endocrine-based therapy or following disease progression on endocrine therapy(Label, NCCN 1);

OR

V. Individual has a diagnosis of recurrent or metastatic endometrial cancer (NCCN 2A); **AND**
VI. Individual is using for systemic therapy; **AND**
VII. Individual is using for ER-positive tumors; **AND**
VIII. Indiidual has lower-grade endometroid histologies (for example in those with small tumor volume or an indolent growth pace); **AND**
IX. Individual is using in combination with letrozole.

Requests for Kisqali Femara (ribociclib succinate/letrozole) Co-Pack may be approved if the following criteria are met:

I. Individual is has a diagnosis of advanced, recurrent, or metastatic breast cancer (Label, NCCN 1); **AND**
II. Individual has hormone receptor-positive, human epidermal growth factor receptor 2-negative (HR+/ HER2-) breast cancer; **AND**
III. Individual is using as initial endocrine-based therapy.

Note: Kisqali is taken for 21 consecutive days in a cycle followed by 7 days off treatment. Warnings and precautions include QT interval prolongation, hepatobiliary toxicity, and neutropenia.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2024. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: Updated periodically.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2024; Updated periodically.
5. Verzenio (abemaciclib) [prescribing information]. Indianapolis, IN: Lilly USA, LLC; October 2021.
6. NCCN Clinical Practice Guidelines in Oncology™. © 2024 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on April 2, 2024.
    a. Breast Cancer. V2.2024. Revised March 11, 2024.
    b. Uterine Neoplasms. V2.2024. Revised March 6, 2024.