Clinical Policy: Ribociclib (Kisqali)

Reference Number: PA.CP.PHAR.334
Effective Date: 01/18
Last Review Date: 07/18

Coding Implications
Revision Log

Description
The intent of the criteria is to ensure that patients follow selection elements established by Pennsylvania Health and Wellness® clinical policy for ribociclib (Kisqali®).

FDA Approved Indication(s)
Kisqali (in combination with an aromatase inhibitor) and Kisqali Femara are 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.

Policy/Criteria
It is the policy of health plans affiliated with Pennsylvania Health and Wellness® that Kisqali is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Breast Cancer (must meet all):

1. Diagnosis of breast cancer;
2. Prescribed by or in consultation with an oncologist;
3. Disease meets all of the following characteristics (a, b, and c):
   a. HR-positive (i.e., estrogen receptor (ER) and/or progesterone receptor (PR) positive);
   b. HER2-negative;
   c. Disease is advanced or metastatic;
4. Prescribed for use in one of the following ways (a or b):
   a. FDA approved use: in combination with an aromatase inhibitor (e.g., letrozole, anastrozole, exemestane) as initial endocrine-based therapy in postmenopausal women;
   b. Off-label NCCN recommended use: male who will receive concomitant treatment for suppression of testicular steroidogenesis;
5. Request meets one of the following (a or b):
   a. Dose does not exceed Kisqali 600 mg per day (3 tablets/day for 21 days) and Femara 2.5 mg per day (1 tablet/day for 28-day cycle);
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

B. Other diagnoses/indications: Refer to PA.CP.PMN.53

II. Continued Approval

A. Breast Cancer (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member has none of the following reasons to discontinue:
   a. Disease progression or unacceptable toxicity;
   b. Required dose reduction to < 200 mg/day.
3. If request is for a dose increase, request meets one of the following (a or b):
   a. New dose does not exceed Kisqali 600 mg/day (3 tablets/day for 21 days) and Femara 2.5 mg/day (1 tablet/day for 28-day cycle);
   b. New dose is supported by practice guideline or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

B. Other diagnoses/indications (1 or 2)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
   Approval duration: per request or 6 months (whichever is less);

2. Refer to PA.CP.PMN.53

Background

Description/Mechanism of Action:
Kisqali is a cyclin-dependent kinase (CDK) 4 and 6 inhibitor. These kinases are activated upon binding to D-cyclins and play a crucial role in signaling pathways which lead to cell cycle progression and cellular proliferation. The cyclin D-CDK4/6 complex regulates cell cycle progression through phosphorylation of the retinoblastoma protein (pRb).

Formulations:
Kisqali tablets: 200 mg

Appendices

Appendix A: Abbreviation Key

CDK: cyclin-dependent kinase
ER: estrogen receptor
HER2: human epidermal growth factor receptor 2
HR: hormone receptor
PR: progesterone receptor

Appendix B: General Information

Doses below 200 mg per day were not included in the clinical trial for Kisqali, and would be potentially sub-therapeutic.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
N/A	

Reviews, Revisions, and Approvals	Date	Approval Date
Added requirement for prescriber specialty. Added criteria for off-label use in men. References reviewed and updated.	02/18	

References

1. Kisqali Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; March 2017. Available at https://www.kisqali.com/. Accessed November 14, 2017.
2. Kisqali Femara Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; May 2017. Available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/209935s000lbl.pdf. Accessed November 14, 2017.
3. National Comprehensive Cancer Network. Breast Cancer Version 3.2017. Available at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed November 14, 2017.
4. Ribociclib. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at www.NCCN.org. Accessed November 14, 2017.