PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Kisqali and Kisqali Femara Co-Pack Prior Authorization Policy
- Kisqali® (ribociclib tablets – Novartis)
- Kisqali® Femara® Co-Pack (ribociclib tablets; letrozole tablets – Novartis)

REVIEW DATE: 01/26/2022; selected revision 06/22/2022

OVERVIEW

Kisqali, a cyclin-dependent kinase (CDK) 4/6 inhibitor, is indicated for the treatment of adults with hormone receptor-positive (HR+), human epidermal growth factor receptor 2 (HER2)-negative **advanced or metastatic breast cancer** in the following settings:[1-3]

- In combination with an aromatase inhibitor (AI) as initial endocrine-based therapy;
- Kisqali (not Co-Pack) in combination with fulvestrant as initial endocrine based therapy or following disease progression on endocrine therapy in postmenopausal women or in men;
- Kisqali Femara Co-Pack has the same indication with the aromatase inhibitor, letrozole being provided.

Guidelines

The National Comprehensive Cancer Network (NCCN) guidelines on breast cancer (version 2.2022– December 20, 2021) recommend any of the CDK4/6 inhibitors in combination with an AI or fulvestrant as a first-line preferred treatment option for HR+ and HER2-negative recurrent unresectable (local or regional) or Stage IV disease in postmenopausal women or premenopausal patient receiving ovarian ablation or suppression (category 1).[3,4] The guidelines state that in phase 3 randomized controlled trials, Kisqali + endocrine therapy has shown overall survival benefit in the first-line setting. CDK4/6 inhibitor + fulvestrant is recommended for second- and subsequent-line therapy, if CDK4/6 inhibitor was not previously used (category 1). However, the guidelines also state in a footnote that if there is disease progression on CDK4/6 inhibitor therapy, there are limited data to support an additional line of therapy with another CDK4/6-containing regimen.[3,4] The guidelines state that in phase 3 randomized controlled trials, fulvestrant in combination with a CDK4/6 inhibitor has shown overall survival benefit in the second-line setting. For men with breast cancer, the compendium recommends they be treated similarly to postmenopausal women, except that the use of an AI is ineffective without concomitant suppression of testicular steroidogenesis.[4]

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Kisqali and Kisqali Femara Co-Pack. All approvals are provided for the duration noted below. In the clinical criteria, as appropriate, an asterisk (*) is noted next to the specified gender. In this context, the specified gender is defined as follows: a woman is defined as an individual with the biological traits of a woman, regardless of the individual's gender identity or gender expression; men are defined as individuals with the biological traits of a man, regardless of the individual's gender identity or gender expression.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Kisqali is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. **Breast Cancer in Women***. Approve for 1 year if the patient meets the following criteria (A, B, C, D, E, and F):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has recurrent or metastatic disease; AND
   - **C)** Patient has hormone receptor positive (HR+) [i.e., estrogen receptor positive {ER+} and/or progesterone receptor positive {PR+}] disease; AND
   - **D)** Patient has human epidermal growth factor receptor 2 (HER2)-negative breast cancer; AND
   - **E)** Patient meets ONE of the following criteria (i or ii):
     - **i.** Patient is postmenopausal; OR
     - **ii.** Patient is pre/perimenopausal and meets one of the following (a or b):
       - **a)** Patient is receiving ovarian suppression/ablation with a gonadotropin-releasing hormone (GnRH) agonist; OR
         Note: Examples of a GnRH agonist include leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant).
       - **b)** Patient has had surgical bilateral oophorectomy or ovarian irradiation; AND
   - **F)** Patient meets ONE of the following criteria (i or ii):
     - **i.** Kisqali will be used in combination with anastrozole, exemestane, or letrozole; OR
     - **ii.** Kisqali will be used in combination with fulvestrant.

   ***** Refer to the Policy Statement.

2. **Breast Cancer in Men*.** Approve for 1 year if the patient meets the following criteria (A, B, C, D, and E):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has recurrent or metastatic disease; AND
   - **C)** Patient has hormone receptor positive (HR+) [i.e., estrogen receptor positive {ER+} and/or progesterone receptor positive {PR+}] disease; AND
   - **D)** Patient has human epidermal growth factor receptor 2 (HER2)-negative breast cancer; AND
   - **E)** Patient meets ONE of the following criteria (i or ii):
     - **i.** Patient meets BOTH of the following criteria (a and b):
       - **a)** Patient is receiving a gonadotropin-releasing hormone (GnRH) analog; AND
         Note: Examples of GnRH analog include leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), Firmagon (degarelix acetate subcutaneous injection), Orgovyx (relugolix tablet).
       - **b)** Kisqali will be used in combination with anastrozole, exemestane, or letrozole; OR
     - **ii.** Kisqali will be used in combination with fulvestrant.

   ***** Refer to the Policy Statement.

II. Coverage of Kisqali Femara Co-Pack is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. **Breast Cancer in Women***. Approve for 1 year if the patient meets the following criteria (A, B, C, D, and E):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has recurrent or metastatic disease; AND
   - **C)** Patient has hormone receptor positive (HR+) [i.e., estrogen receptor positive {ER+} and/or progesterone receptor positive {PR+}] disease; AND
   - **D)** Patient has human epidermal growth factor receptor 2 (HER2)-negative breast cancer; AND
   - **E)** Patient meets ONE of the following criteria (i or ii):
     - **i.** Patient is postmenopausal OR
     - **ii.** Patient is pre/perimenopausal and meets one of the following (a or b):
       - **a)** Patient is receiving ovarian suppression/ablation with a gonadotropin-releasing hormone (GnRH) agonist; OR
         Note: Examples of a GnRH agonist include leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant).
       - **b)** Patient has had surgical bilateral oophorectomy or ovarian irradiation.

   ***** Refer to the Policy Statement.

2 **Breast Cancer in Men*.** Approve for 1 year if the patient meets the following criteria (A, B, C, D, and E):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has recurrent or metastatic disease; AND
   - **C)** Patient has hormone receptor positive (HR+) [i.e., estrogen receptor positive {ER+} and/or progesterone receptor positive {PR+}] disease; AND
   - **D)** Patient has human epidermal growth factor receptor 2 (HER2)-negative breast cancer; AND
   - **E)** Patient is receiving a gonadotropin-releasing hormone (GnRH) analog.
     Note: Examples of a GnRH analog include leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), Firmagon (degarelix acetate subcutaneous injection), Orgovyx (relugolix tablet).

   ***** Refer to the Policy Statement.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Kisqali or Kisqali Femara Co-Pack is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Kisqali® tablets [prescribing information]. East Hanover, NJ: Novartis; December 2021
2. Kisqali® Femara® Co-Pack tablets [prescribing information]. East Hanover, NJ: Novartis; December 2021.
3. The NCCN Breast Cancer Clinical Practice Guidelines in Oncology (version 2.2022 – December 20, 2021). © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 19, 2022.
4. The NCCN Compendium. © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Search term: ribociclib. Accessed on January 19, 2022.

GnRH – Gonadotropin- releasing hormone.