FORMULARY EXCEPTION POLICY

POLICY: Kisqali® (ribociclib tablets – Pfizer Labs)
       Kisqali® Femara® Co-Pack (ribociclib tablets; letrozole tablets, co-pack for oral use – Pfizer Labs)

DATE REVISED: 06/05/2019 (EFFECTIVE 07/01/2019)

POLICY STATEMENT
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.

Documentation: Documentation will be required for patients requesting Kisqali/Kisqali Femara Co-Pack where noted in the criteria as [documentation required]. Documentation may include, but is not limited to, chart notes, prescription claims records, prescription receipts and/or laboratory data.

KISQALI CRITERIA

1. Breast Cancer in Postmenopausal Women*. Approve for 1 year if the patient meets the following criteria (A, B, C, D, and E):
   A) Patient has advanced or metastatic hormone receptor positive (HR+) [i.e., estrogen receptor positive (ER+) and/or progesterone receptor positive (PR+)] disease; AND
   B) Patient has human epidermal growth factor receptor 2 (HER2)-negative breast cancer; AND
   C) The 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 Faslodex® (fulvestrant intramuscular injection); AND
   D) The patient has not had disease progression while on Kisqali, Ibrance (palbociclib capsules), or Verzenio (abemaciclib tablets); AND
   E) The patient meets ONE of the following criteria (i or ii):
      i. The patient has been taking Kisqali and is continuing therapy [documentation required]; OR
      ii. If Kisqali is used in combination with Faslodex, it is used as initial endocrine-based therapy.

* Refer to the Policy Statement.

2. Breast Cancer in Pre/Perimenopausal Women*. Approve for 1 year if the patient meets the following criteria (A, B, C, D, and E):
   A) Patient has advanced or metastatic hormone receptor positive (HR+) [i.e., estrogen receptor positive (ER+) and/or progesterone receptor positive (PR+)] disease; AND
   B) Patient has human epidermal growth factor receptor 2 (HER2)-negative breast cancer; AND
   C) Patient meets one of the following criteria (i, ii, or iii):
      i. The patient meets both of the following criteria (a and b):
         a) Kisqali will be used in combination with anastrozole, exemestane, or letrozole; AND
         b) Patient is receiving ovarian suppression/ablation with a gonadotropin-releasing hormone (GnRH) agonist (e.g., Lupron [leuprolide], Trelstar [triptorelin], Zoladex [goserelin]), or has had surgical bilateral oophorectomy or ovarian irradiation; OR
      ii. Kisqali will be used in combination with Faslodex; OR
      iii. Kisqali is used in combination with tamoxifen as first-line therapy; AND
D) Patient has not had disease progression while on Kisqali, Ibrance (palbociclib capsules), or Verzenio (abemaciclib tablets); AND
E) The patient meets ONE of the following criteria (i, ii, or iii):
   i. The patient has been taking Kisqali and is continuing therapy [documentation required]; OR
   ii. If Kisqali is used in combination with an aromatase inhibitor it is used as initial endocrine-based therapy; OR
   iii. Kisqali will be used in combination with tamoxifen.

* Refer to the Policy Statement.

3. Breast Cancer in Men*. Approve for 1 year if the patient meets the following criteria (A, B, C, D, and E):
   A) Patient has advanced or metastatic hormone receptor positive (HR+) [i.e., estrogen receptor positive {ER+} and/or progesterone receptor positive {PR+}] disease; AND
   B) Patient has human epidermal growth factor receptor 2 (HER2)-negative breast cancer; AND
   C) 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) agonist (e.g., Lupron [leuprolide], Trelstar [triptorelin], Zoladex (goserelin)); AND
         b) Kisqali will be used in combination with anastrozole, exemestane, or letrozole; OR
      ii. Kisqali will be used in combination with Faslodex® (fulvestrant intramuscular injection); AND
   D) Patient has not had disease progression while on Kisqali, Ibrance (palbociclib capsules), or Verzenio (abemaciclib tablets); AND
   E) The patient meets ONE of the following criteria (i or ii):
      i. The patient has been taking Kisqali and is continuing therapy [documentation required]; OR
      ii. If Kisqali is used in combination with Faslodex, it is used as initial endocrine-based therapy.

* Refer to the Policy Statement.

Kisqali Femara Co-Pack Criteria

4. Breast Cancer in Women*. Approve for 1 year if the patient meets the following criteria (A, B, C, D, and E):
   A) Patient has advanced or metastatic hormone receptor positive (HR+) [i.e., estrogen receptor positive {ER+} and/or progesterone receptor positive {PR+}] disease; AND
   B) Patient has human epidermal growth factor receptor 2 (HER2)-negative breast cancer; AND
   C) If the patient is premenopausal or perimenopausal, then the patient is receiving ovarian suppression/ablation with a gonadotropin-releasing hormone (GnRH) agonist (e.g., Lupron [leuprolide], Trelstar [triptorelin], Zoladex (goserelin)), or has had surgical bilateral oophorectomy or ovarian irradiation; AND
   D) The patient has not had disease progression while on Kisqali, Ibrance (palbociclib capsules), or Verzenio (abemaciclib tablets); AND
   E) The patient meets ONE of the following criteria (i or ii):
      i. The patient has been taking Kisqali Femara Co-Pack and is continuing therapy [documentation required]; OR
      ii. If the patient is pre/perimenopausal, Kisqali Femara Co-Pack is used as initial endocrine-based therapy.

* Refer to the Policy Statement.
5. **Breast Cancer in Men**. Approve for 1 year if the patient meets the following criteria (A, B, C, D, and E):

A) Patient has advanced or metastatic hormone receptor positive (HR+) [i.e., estrogen receptor positive (ER+) and/or progesterone receptor positive (PR+)] disease; AND

B) Patient has human epidermal growth factor receptor 2 (HER2)-negative breast cancer; AND

C) The patient is receiving a gonadotropin-releasing hormone (GnRH) agonist (e.g., Lupron [leuprolide], Trelstar [triptorelin], Zoladex [goserelin]); AND

D) The patient has not had disease progression while on Kisqali, Ibrance (palbociclib capsules), or Verzenio (abemaciclib tablets); AND

E) The patient has been taking Kisqali Femara Co-Pack and is continuing therapy [documentation required].

* Refer to the Policy Statement.

**HISTORY**

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<th>Date Revised</th>
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