VENTURA COUNTY
HEALTH CARE PLAN

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: 07/14/2020

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 fulvestrant; 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 fulvestrant, 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 or ii):
     - **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 fulvestrant; 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 an aromatase inhibitor it is used as initial endocrine-based therapy.

* 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 fulvestrant; 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 fulvestrant, 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

Type of Revision	Summary of Changes*	Date Revised
New Policy	--	06/05/2019
Annual revision	Criteria for Kisqali use in combination with tamoxifen as first-line therapy has been deleted for pre/perimenopausal women since it is no longer supported in guidelines due to QTc prolongation.	07/14/2020