RIBOCICLIB

Generic	Brand	HICL	GCN	Exception/Other
RIBOCICLIB	KISQALI	44151		
RIBOCICLIB LETROZOLE	KISQALI FEMARA CO-PACK	44246		

GUIDELINES FOR USE

1. Is the request for Kisqali-Femara Co-Pack?

   If yes, continue to #2.
   If no, continue to #5.

2. Does the patient have a diagnosis of advanced or metastatic breast cancer that is hormone receptor (HR)-positive and human epidermal growth factor receptor 2 (HER2)-negative and meet **ALL** of the following criteria?
   - The patient is female
   - The patient has **NOT** received prior endocrine-based therapy for advanced or metastatic breast cancer (e.g., letrozole, anastrozole, tamoxifen, fulvestrant, exemestane)
   - The patient has **NOT** experienced disease progression following prior CDK inhibitor therapy

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Is the patient pre/perimenopausal?

   If yes, **approve Kisqali-Femara Co-Pack for 12 months by GPID for all daily dosage strengths with the following quantity limits:**
   - **200mg daily dose (Co-Pack) (GPID 43366): #49 tablets per 28 days.**
   - **400mg daily dose (Co-Pack) (GPID 43368): #70 tablets per 28 days.**
   - **600mg daily dose (Co-Pack) (GPID 43369): #91 tablets per 28 days.**

   If no, continue to #4.

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GUIDELINES FOR USE (CONTINUED)

4. Is the patient post-menopausal **AND** meets the following criterion?
   - The patient had a trial of Ibrance (palbociclib) **OR** Verzenio (abemaciclib)

   If yes, **approve Kisqali-Femara Co-Pack for 12 months by GPID for all daily dosage strengths with the following quantity limits:**
   - **200mg daily dose (Co-Pack) (GPID 43366): #49 tablets per 28 days.**
   - **400mg daily dose (Co-Pack) (GPID 43368): #70 tablets per 28 days.**
   - **600mg daily dose (Co-Pack) (GPID 43369): #91 tablets per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

5. Is the request for Kisqali?

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline

6. Does the patient have a diagnosis of advanced or metastatic breast cancer that is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative and meet **ALL** of the following criteria?
   - The patient is female
   - The requested medication will be used in combination with an aromatase inhibitor (e.g., letrozole, anastrozole, or exemestane)
   - The patient has **NOT** received prior endocrine-based therapy for advanced or metastatic breast cancer (e.g., letrozole, anastrozole, tamoxifen, fulvestrant, exemestane)
   - The patient has **NOT** experienced disease progression following prior CDK inhibitor therapy

   If yes, continue to #7.
   If no, continue to #9.

7. Is the patient pre/perimenopausal?

   If yes, **approve Kisqali for 12 months by GPID for all daily dosage strengths with the following quantity limits:**
   - **200mg daily dose (GPID 43162): #21 tablets per 28 days.**
   - **400mg daily dose (GPID 43166): #42 tablets per 28 days.**
   - **600mg daily dose (GPID 43167): #63 tablets per 28 days.**

   If no, continue to #8.

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GUIDELINES FOR USE (CONTINUED)

8. Is the patient post-menopausal **AND** meets the following criterion?
   - The patient had a trial of Ibrance (palbociclib) **OR** Verzenio (abemaciclib)

   If yes, **approve Kisqali for 12 months by GPID for all daily dosage strengths with the following quantity limits:**
   - **200mg daily dose (GPID 43162): #21 tablets per 28 days.**
   - **400mg daily dose (GPID 43166): #42 tablets per 28 days.**
   - **600mg daily dose (GPID 43167): #63 tablets per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

9. Does the patient have a diagnosis of advanced or metastatic breast cancer that is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative and meet **ALL** of the following criteria?
   - The patient is female and postmenopausal
   - The requested medication will be used in combination with Faslodex (fulvestrant)
   - The patient has **NOT** experienced disease progression following prior CDK inhibitor therapy

   If yes, continue to #10.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

10. Is the request for a patient that has **NOT** received prior endocrine-based therapy for advanced or metastatic breast cancer (e.g., letrozole, anastrozole, tamoxifen, fulvestrant, exemestane)?

    If yes, **approve Kisqali for 12 months by GPID for all daily dosage strengths with the following quantity limits:**
    - **200mg daily dose (GPID 43162): #21 tablets per 28 days.**
    - **400mg daily dose (GPID 43166): #42 tablets per 28 days.**
    - **600mg daily dose (GPID 43167): #63 tablets per 28 days.**

    If no, continue to #11.

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GUIDELINES FOR USE (CONTINUED)

11. Is the request for a patient that has experienced disease progression on endocrine therapy **AND** meets the following criterion?
    - The patient had a trial of Ibrance (palbociclib) **OR** Verzenio (abemaciclib)

    If yes, **approve Kisqali for 12 months by GPID for all daily dosage strengths with the following quantity limits:**
    - **200mg daily dose (GPID 43162): #21 tablets per 28 days.**
    - **400mg daily dose (GPID 43166): #42 tablets per 28 days.**
    - **600mg daily dose (GPID 43167): #63 tablets per 28 days.**

    If no, do not approve.
    DENIAL TEXT: The guideline named **RIBOCICLIB (Kisqali, Kisqali/Femara co-pack)** requires a diagnosis of advanced or metastatic breast cancer that is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative. In addition, the following criteria must be met:
    For Kisqali-Femara Co-Pack request, approval requires:
    - The patient is female
    - The patient has **NOT** received prior endocrine-based therapy for advanced or metastatic breast cancer (e.g., letrozole, anastrozole, tamoxifen, fulvestrant, exemestane)
    - The patient has **NOT** experienced disease progression following prior CDK inhibitor therapy
    - The patient meets **ONE** of the following:
      - The patient is pre/perimenopausal
      - The patient is post-menopausal and has had a trial of Ibrance (palbociclib) or Verzenio (abemaciclib)

    For Kisqali request, approval requires ONE of the following:
    - **Kisqali will be used in combination with an aromatase inhibitor and meet all of the following:**
      - The patient is female
      - The patient has **NOT** received prior endocrine-based therapy for advanced or metastatic breast cancer (e.g., letrozole, anastrozole, tamoxifen, fulvestrant, exemestane)
      - The patient has **NOT** experienced disease progression following prior CDK inhibitor therapy
      - The patient meets **ONE** of the following:
        - The patient is pre/perimenopausal
        - The patient is post-menopausal and has had a trial of Ibrance (palbociclib) or Verzenio (abemaciclib)

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GUIDELINES FOR USE (CONTINUED)

- **Kisqali will be used in combination with Faslodex (fulvestrant) and meet all of the following:**
  - The patient is female and post-menopausal
  - The patient has **NOT** experienced disease progression following prior CDK inhibitor therapy
  - The patient meets **ONE** of the following:
    - The patient has **NOT** received prior endocrine-based therapy for advanced or metastatic breast cancer (e.g., letrozole, anastrozole, tamoxifen, fulvestrant, exemestane)
    - The patient has experienced disease progression on endocrine therapy **AND** has had a trial of Ibrance (palbociclib) or Verzenio (abemaciclib)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Kisqali or Kisqali/Femara Co-Pack.

REFERENCES

- Kisqali [Prescribing Information]. East Hanover, NJ. Novartis; July 2018.
- Kisqali/Femara Co-Pack [Prescribing Information]. East Hanover, NJ. Novartis; February 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/19
Created: 05/17
Client Approval: 03/19
P&T Approval: 01/19