



STANDARD COMMERCIAL DRUG FORMULARY  
PRIOR AUTHORIZATION GUIDELINES

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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STANDARD COMMERCIAL DRUG FORMULARY  
PRIOR AUTHORIZATION GUIDELINES

RIBOCICLIB

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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STANDARD COMMERCIAL DRUG FORMULARY  
PRIOR AUTHORIZATION GUIDELINES

RIBOCICLIB

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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STANDARD COMMERCIAL DRUG FORMULARY  
PRIOR AUTHORIZATION GUIDELINES

RIBOCICLIB

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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STANDARD COMMERCIAL DRUG FORMULARY  
PRIOR AUTHORIZATION GUIDELINES

RIBOCICLIB

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.

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Yes	Yes	No

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