

Cigna National Preferred Formulary Coverage Policy



Effective Date 1/1/2021

Next Review Date... 1/1/2022

Coverage Policy Number NPF015

Formulary Exception

Kisqali® (ribociclib tablets), Kisqali® Femara Co-Pack (ribociclib tablets; letrozole tablets, co-pack for oral use)

Table of Contents

NPF Coverage Policy	1
References	3
Last Revision Details	3

Related Coverage Resources

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

NPF Coverage Policy

Cigna covers ribociclib (Kisqali®) or ribociclib-letrozole (Kisqali® Femara Co-Pack) as medically necessary when the following criteria are met:

Kisqali Criteria

- 1. Breast Cancer in Postmenopausal Women.** Approve for 1 year if the individual meets the following criteria (A, B, C, D, and E):
 - A)** Individual has advanced or metastatic hormone receptor positive (HR+) [i.e., estrogen receptor positive {ER+} and/or progesterone receptor positive {PR+}] disease; AND
 - B)** Individual has human epidermal growth factor receptor 2 (HER2)-negative breast cancer; AND
 - C)** The individual 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 individual has not had disease progression while on Kisqali, Ibrance (palbociclib capsules), or Verzenio (abemaciclib tablets); AND
- E) The individual meets ONE of the following criteria (i or ii):
 - i. The individual 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.

2. Breast Cancer in Pre/Perimenopausal Women. Approve for 1 year if the individual meets the following criteria (A, B, C, D, and E):

- A) Individual has advanced or metastatic hormone receptor positive (HR+) [i.e., estrogen receptor positive {ER+} and/or progesterone receptor positive {PR+}] disease; AND
- B) Individual has human epidermal growth factor receptor 2 (HER2)-negative breast cancer; AND
- C) Individual meets one of the following criteria (i or ii):
 - i. The individual meets both of the following criteria (a and b):
 - a) Kisqali will be used in combination with anastrozole, exemestane, or letrozole; AND
 - b) Individual 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) Individual has not had disease progression while on Kisqali, Ibrance (palbociclib capsules), or Verzenio (abemaciclib tablets); AND
- E) The individual meets ONE of the following criteria (i or ii):
 - i. The individual 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.

3. Breast Cancer in Men. Approve for 1 year if the individual meets the following criteria (A, B, C, D, and E):

- A) Individual has advanced or metastatic hormone receptor positive (HR+) [i.e., estrogen receptor positive {ER+} and/or progesterone receptor positive {PR+}] disease; AND
- B) Individual has human epidermal growth factor receptor 2 (HER2)-negative breast cancer; AND
- C) Individual meets ONE of the following criteria (i or ii):
 - i. Individual meets BOTH of the following criteria (a and b):
 - a) Individual 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) Individual has not had disease progression while on Kisqali, Ibrance (palbociclib capsules), or Verzenio (abemaciclib tablets); AND
- E) The individual meets ONE of the following criteria (i or ii):
 - i. The individual 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.

Kisqali Femara Co-Pack Criteria

4. Breast Cancer in Women. Approve for 1 year if the individual meets the following criteria (A, B, C, D, and E):

- A) Individual has advanced or metastatic hormone receptor positive (HR+) [i.e., estrogen receptor positive {ER+} and/or progesterone receptor positive {PR+}] disease; AND
- B) Individual has human epidermal growth factor receptor 2 (HER2)-negative breast cancer; AND
- C) If the individual is premenopausal or perimenopausal, then the individual 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 individual has not had disease progression while on Kisqali, Ibrance (palbociclib capsules), or Verzenio (abemaciclib tablets); AND
- E) The individual meets ONE of the following criteria (i or ii):

- i. The individual has been taking Kisqali Femara Co-Pack and is continuing therapy [documentation required]; OR
- ii. If the individual is pre/perimenopausal, Kisqali Femara Co-Pack is used as initial endocrine-based therapy.

- 5. Breast Cancer in Men.** Approve for 1 year if the individual meets the following criteria (A, B, C, D, and E):
- A)** Individual has advanced or metastatic hormone receptor positive (HR+) [i.e., estrogen receptor positive {ER+} and/or progesterone receptor positive {PR+}] disease; AND
 - B)** Individual has human epidermal growth factor receptor 2 (HER2)-negative breast cancer; AND
 - C)** The individual is receiving a gonadotropin-releasing hormone (GnRH) agonist (e.g., Lupron [leuprolide], Trelstar [triptorelin], Zoladex [goserelin]); AND
 - D)** The individual has not had disease progression while on Kisqali, Ibrance (palbociclib capsules), or Verzenio (abemaciclib tablets); AND
 - E)** The individual has been taking Kisqali Femara Co-Pack and is continuing therapy [documentation required].

Documentation: Documentation will be required for individuals 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.

Conditions Not Covered

Ribociclib (Kisqali®) or ribociclib-letrozole (Kisqali® Femara Co-Pack) is considered experimental, investigational or unproven for ANY other use.

References

1. U.S. Food and Drug Administration. Drugs@FDA. U.S. Department of Health & Human Services: <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/>

Last Revision Details

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
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