Ribociclib Succinate

Adjudication Guideline

Rule Category:	Ref: No:	Version Control:	Effective Date:	Revision Date:
Pharmaceutical	2023-PH-0026	Version No.4	01/04/2024	29/07/2026

Approved by:	Responsible:	Related Adjudication Guidelines:
Daman	Pharmaceutical Standards & Governance	N/A

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1. Abstract

1.1 For Members

Ribociclib Succinate is a kinase inhibitor indicated for the treatment of adult patients with hormone receptor (HR) positive, in combination with an aromatase inhibitor as initial endocrine-based therapy for the treatment of: -

1. Postmenopausal women with hormone receptor (HR)-positive,
2. Human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer.
3.Human epidermal growth factor receptor 2 (HER2)-negative stage II and III early breast cancer at high risk of recurrence.

1.2 For Medical Professionals

Ribociclib succinate will be reviewed by High-cost team, relevant reports pertaining to treatment history, frequency, and dosage for the indications should be delivered upon request for further review.

Relevant clinicians are only permitted to order the medication.

Dosage and Administration:

Tablets are taken orally with or without food in combination with an aromatase inhibitor or fulvestrant.

Early Breast Cancer
Recommended starting dose: 400 mg orally (two 200 mg tablets) taken once daily with or without food for 21 consecutive days followed by 7 days off treatment.

Advanced or Metastatic Breast Cancer
Recommended starting dose: 600 mg orally (three 200 mg tablets) taken once daily with or without food for 21 consecutive days followed by 7 days off treatment

2. Scope

The scope of this adjudication rule is to highlight the medical indications, and coverage details for Ribociclib Succinate as per the policy terms and conditions of each health insurance plan administered by Daman.

3. Adjudication Policy

3.1 Eligibility / Coverage Criteria

1. Ribociclib Succinate is a kinase inhibitor indicated for the treatment of adult patients with hormone receptor (HR) positive, in combination with an aromatase inhibitor as initial endocrine-based therapy for the treatment of:

    - Postmenopausal women with hormone receptor (HR)-positive,
    - Human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer

    - Human epidermal growth factor receptor 2 (HER2)-negative stage II and III early breast cancer at high risk of recurrence.

2. The safety and efficacy of Ribociclib succinate in Pediatric patients has not been established.
3. It has plan-wise coverage and can be billed based on medical necessity.
4. Ribociclib Succinate is administered in 28-day treatment cycles (21 days on treatment followed by 7 days off). The recommended starting dose is 400 mg once daily for early breast cancer and 600 mg once daily for advanced or metastatic breast cancer

3.2 Requirements for Coverage

All the relevant documents should be submitted upon request, also providing the history of treatment, the frequency or dosage related to the same.

3.3 Non-Coverage

Covered by all plans except visitor's plan.

3.4 Payment and Coding Rules

Please apply regulator payment rules and regulations and relevant coding manuals for ICD, CPT, etc. Kindly code the ICD-10 and the CPT codes to the highest level of specificity.

Table 1: Eligible clinicians

Eligible Category
Radiation Oncology
Medical Oncology
Surgical Oncology
Gynaecology Oncology

4. Denial Codes

DOH denial codes with description are elaborated for reference. These are specialized codes directed by DOH, that explains the reason of rejection of the service by DAMAN to the providers.

Code	Code Description
MNEC 003	Diagnoses are not covered
MNEC 004	Service is not clinically indicated based on good clinical practice
CODE-010	Activity/diagnosis inconsistent with clinician's specialty
CLN-001	Activity/diagnosis inconsistent with clinician specialty
NCOV-003	Service(s) is (are) not covered

5. Appendices

5.1 References

https://www.ema.europa.eu/en/medicines/human/EPAR/kisqali
https://www.medicines.org.uk/emc/product/8110/smpc#gref
https://www.ema.europa.eu/en/documents/product-information/kisqali-epar-product- information_en.pdf
https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/209092s009lbl.pdf
https://clinicaltrials.gov/ct2/show/NCT03078751
https://clinicaltrials.gov/ct2/show/NCT03701334
https://go.drugbank.com/drugs/DB11730
https://www.chemoexperts.com/ribociclib-kisqali-letrozole-femara-breast-cancer.html#tip2
https://www.tga.gov.au/sites/default/files/auspar-ribociclib-succinate-200630.pdf
https://www.medicines.org.uk/emc/product/8110/smpc#gref
https://www.accessdata.fda.gov/drugsatfda_docs/label/2026/209092s027lbl.pdf

5.2 Revision History

Date	Version No.	Change(s)
01/04/2024	V1.0	New Version
11/12/2024	V2.0	Update-New diagnosis added as per FDA reference
24/07/2025	V3.0	AR review-No changes
29/07/2026	V4.0	Guideline review- dose for early breast cancer incorporated as per FDA reference; new reference added

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