Ribociclib Succinate

Adjudication Guideline

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Approved by:	Responsible:	Related Adjudication Guidelines:
Daman	Medical Standards & Research	

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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.

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.

Recommended starting dose:

- 600 mg orally (three 200 mg tablets) taken constipation, rash, and cough. once daily with or without food for 21 consecutive days followed by 7 days off treatment.
- Dose interruption, reduction, and/or discontinuation may be required based on individual safety and tolerability.

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.

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. Three Ribociclib tablets a day for 21 days, followed by a seven-day break. This is a complete cycle. The cycle is then repeated. The maximum daily recommended dose is 600mg (three 200mg tablets).

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

5.2 Revision History

Date	Change(s)
01.04.2024	New Version