KISQALI - NCCN recommendations - HCP

Prescribing information

Image

Image

National Comprehensive Cancer Network® (NCCN®) recommendations

Indications:[1]

- KISQALI® (ribociclib) is indicated for the treatment of women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer in combination with an aromatase inhibitor or fulvestrant as initial endocrine-based therapy, or in women who have received prior endocrine therapy

- In pre- or perimenopausal women, the endocrine therapy should be combined with a luteinising hormone-releasing hormone (LHRH) agonist

KISQALI is not recommended to be used in combination with tamoxifen.

To learn more about the safety profile of KISQALI, visit our portal page here.

For full safety profile information, please refer to the KISQALI Summary of Product Characteristics.

The National Comprehensive Cancer Network (NCCN) is a not-for-profit alliance of 33 leading US cancer centres, providing resources used in more than 190 countries.[2]

NCCN clinical practice guidelines in oncology (NCCN Guidelines®): Breast cancer

NCCN recommendations for KISQALI in HR+/HER2– recurrent, unresectable or stage IV (M1) breast cancer:[3,4]

Image

KISQALI is a Category 1-rated CDK4/6i in combination with either AI and fulvestrant[3,4]

Category 1: Based upon high-level evidence (≥1 randomised Phase III trials or high-quality, robust meta-analyses), there is uniform NCCN consensus (≥85% support of the panel) that the intervention is appropriate.[4]

Image

KISQALI + ET is recommended in eligible patients with HR+/HER2– aBC[3,4]

ET is defined as AI or fulvestrant.[3,4]

KISQALI is not recommended to be used in combination with tamoxifen.[1]

How are the NCCN guidelines developed and updated?[5]

- Recommendations are derived from critical evaluation of evidence, integrated with the clinical expertise and consensus of a multidisciplinary panel of experts and researchers
- Panels evaluate the efficacy and toxicity of interventions
- Recommendations are agreed upon by panel members
- NCCN categories for recommendations are based on the level of clinical evidence available and the degree of consensus within the panel

View the table below to learn more about the NCCN categories of evidence and consensus.

NCCN categories of evidence and consensus[4]

Category 1	Based upon high-level evidence (≥1 randomised Phase III trials or high-quality, robust meta-analyses), there is uniform NCCN consensus (≥85% support of the panel) that the intervention is appropriate
Category 2A	Based upon lower-level evidence, there is uniform NCCN consensus (≥85% support of the panel) that the intervention is appropriate
Category 2B	Based upon lower-level evidence, there is uniform NCCN consensus (≥50%, but <85% support of the panel) that the intervention is appropriate
Category 3	Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate

1L, first-line; aBC, advanced breast cancer; AI, aromatase inhibitor; CDK4/6i, cyclin-dependent kinase 4/6 inhibitor; HER2–, human epidermal growth receptor 2-negative; HR+, hormone receptor-positive; LHRH, luteinising hormone-releasing hormone; NCCN, National Comprehensive Cancer Network; US, United States.

References:

1. KISQALI® (ribociclib) Summary of Product Characteristics.

2. National Comprehensive Cancer Network. Home page. Available at: https://www.nccn.org/ [Accessed March 2025].

3. National Comprehensive Cancer Network. NCCN Guidelines Insights: Breast Cancer Version 4.2023. Available at: https://jnccn.org/view/journals/jnccn/21/6/article-p594.xml [Accessed March 2025].

4. National Comprehensive Cancer Network. Breast Cancer Guidelines Version 1.2025. Available at: https://www.nccn.org/guidelines/guidelines-detail?category=1&id=1419 [Accessed March 2025].

5. National Comprehensive Cancer Network. Development and Update of Guidelines. Available at: https://www.nccn.org/guidelines/guidelines-process/development-and-update-of-guidelines [Accessed March 2025].

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