

Specialty Pharmacy Program

Xeloda® (capecitabine)

DESCRIPTION

Xeloda is an oral prodrug of 5-fluorouracil (5-FU), an antimetabolite antineoplastic agent. Xeloda is indicated for the treatment of colorectal cancer and breast cancer.

APPROVAL DURATION

Approval duration: 1 year

APPROVAL CRITERIA

FDA-Approved Indication(s)

1. Colorectal cancer
 - a. Adjuvant treatment, as a single agent, in patients with Dukes' C colon cancer who have undergone complete resection of the primary tumor when treatment with fluoropyrimidine therapy alone is preferred.
 - b. First-line treatment of patients with metastatic colorectal carcinoma when treatment with fluoropyrimidine therapy alone is preferred.
2. Breast cancer
 - a. Treatment of patients with metastatic breast cancer after failure of prior anthracycline-containing chemotherapy, in combination with docetaxel.
 - b. Monotherapy treatment of patients with metastatic breast cancer resistant to both paclitaxel and an anthracycline-containing chemotherapy regimen or resistant to paclitaxel and for whom further anthracycline therapy is not indicated.

Off-Label Indication(s)

Requests for off-label use of Xeloda will be reviewed and approved when sufficiently supported by evidence from major compendia, published peer-reviewed medical literature, nationally accepted practice guidelines, or expert consensus statements. The major compendia that are recognized include AHFS® Drug Information, Thomson Micromedex®, National Comprehensive Cancer Network Drugs and Biologics Compendium™, and Clinical Pharmacology.