

Prior Authorization DRUG Guidelines

Xeloda (capecitabine)

Effective Date: 01/24/17

Developed 11/30/16 by R. Sterling, MD

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XELODA (capecitabine) is a fluoropyrimidine carbamate with antineoplastic activity. It is an orally administered systemic prodrug of 5'-deoxy-5-fluorouridine which is converted to 5-fluorouracil. It is often used in combination with other antineoplastic drugs.

Pre-authorization Criteria:

Metastatic breast cancer:

Monotherapy: Treatment of metastatic breast cancer resistant to both paclitaxel (Taxol) and an anthracycline-containing regimen (e.g. Adriamycin), or resistant to paclitaxel in patients for whom further anthracycline therapy is not indicated

Combination therapy: Treatment of metastatic breast cancer (in combination with docetaxel [Taxotere]) after failure of a prior anthracycline-containing regimen

Metastatic colorectal cancer: First-line treatment of metastatic colorectal cancer when treatment with a fluoropyrimidine alone is preferred; adjuvant therapy of Dukes' C colon cancer after complete resection of the primary tumor when fluoropyrimidine therapy alone is preferred

Dosing:

Breast cancer: oral 1,250 mg/m² twice daily for 2 weeks, every 21 days (as either monotherapy or in combination with docetaxel)

Colorectal cancer: oral 1,250 mg/m² twice daily for 2 weeks, every 21 days

Note: Use in other cancers is off-label. Please see the VCHCP Coverage of Prescription Medication for Off-Label Use policy.

How Supplied: tablets 150 mg, 500 mg

Adverse Reactions/Precautions: Black Box Warning (potentiates the effect of warfarin); bone marrow suppression; cardiotoxicity; hepatotoxicity diarrhea; hand and foot syndrome (palmar-plantar erythrodysesthesia);

Drug Interactions: capecitabine inhibits CYP2C9; use caution with other drugs metabolized by CYP2C9 (e.g. cannabis, carvedilol, diclofenac, fosphenytoin, phenytoin, some Q-T prolonging drugs); some drugs may decrease effectiveness of capecitabine (e.g. PPIs)

REFERENCES:

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Cassidy J, Tabernero J, Twelves C, et al, "XELOX (Capecitabine Plus Oxaliplatin): Active First-Line Therapy for Patients With Metastatic Colorectal Cancer," *J Clin Oncol*, 2004, 22(11):2084-91.

Cassidy J, Twelves C, Van Cutsem E, et al. First-line oral capecitabine therapy in metastatic colorectal cancer: a favorable safety profile compared with intravenous 5-fluorouracil/leucovorin. *Ann Oncol*. 2002;13(4):566-575.

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