VENTURA COUNTY
HEALTH CARE PLAN

Xeloda (capecitabine)

Effective Date: 01/24/17

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

Last Approval Date: 1/24/17, 1/23/18, 1/22/19, 2/18/20, 2/2/2, 8/3/21, 2/1/22

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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:
5,600 mg/day (in 2 divided doses) in patients with a body surface area of ≥2.18 m^2 for labeled indications (refer to product labeling for details). Baseline platelets should be ≥100,000/mm^3 and neutrophils should be ≥1,500/mm^3 prior to capecitabine initiation.
NOTE: The elderly may be more sensitive to the toxic effects of fluorouracil.

***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)

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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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UpToDate 2017: Capecitabine: Drug information

1. Nerlynx (capecitabine) [prescribing information]. Los Angeles, CA: Puma Biotechnology; July 2020.
2. Saura C, Oliveira M, Feng YH, et al; NALA Investigators. Neratinib plus capecitabine versus lapatinib plus capecitabine in HER2-positive metastatic breast cancer previously treated with ≥ 2 HER2-directed regimens: phase III NALA trial. J Clin Oncol. 2020;38(27):3138-3149.

3. Griggs JJ, Bohlke K, Balaban EP, et al. Appropriate systemic therapy dosing for obese adult patients with cancer: ASCO guideline update. J Clin Oncol. Published online May 3, 2021.

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Revision Date	Content Revised (Yes/No)	Contributors	Review/Revision Notes
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1/31/23	Yes	Howard Taekman, MD; Robert Sterling, MD	Archived; ESI drug policy became available.