

for XELODA[®]
(capecitabine)

SAMPLE CODING

Dukes' C Colon Cancer

TYPE	CODE		DESCRIPTION
Diagnosis: ICD-10-CM	C18.0		Malignant neoplasm of cecum
	C18.2–C18.9		Malignant neoplasm of the colon, by site
Drug: NDC Note: Payer requirements regarding use of a 10-digit or 11-digit NDC may vary. Both formats are listed here for your reference.	10-digit	11-digit	
	0004-1101-50	00004-1101-50	500 mg (120 film-coated tablets in 1 bottle, plastic)
	0004-1100-20	00004-1100-20	150 mg (60 film-coated tablets in 1 bottle, plastic)

ICD-10-CM=International Classification of Diseases, 10th Revision, Clinical Modification; NDC=National Drug Code.

These codes are not all-inclusive; appropriate codes can vary by patient, setting of care and payer. Correct coding is the responsibility of the provider submitting the claim for the item or service. Please check with the payer to verify codes and special billing requirements. Genentech does not make any representation or guarantee concerning reimbursement or coverage for any service or item.

Many payers will not accept unspecified codes. If you use an unspecified code, please check with your payer.

INDICATIONS & IMPORTANT SAFETY INFORMATION

INDICATIONS AND USAGE

Colorectal Cancer

Xeloda is indicated as a single agent for adjuvant treatment in patients with Dukes' C colon cancer who have undergone complete resection of the primary tumor when treatment with fluoropyrimidine therapy alone is preferred. Xeloda was non-inferior to 5-fluorouracil and leucovorin (5-FU/LV) for disease-free survival (DFS). Physicians should consider results of combination chemotherapy trials, which have shown improvement of DFS and OS, when prescribing single-agent Xeloda in the adjuvant treatment of Dukes' C colon cancer.

Xeloda is indicated as first-line treatment of patients with metastatic colorectal carcinoma when treatment with fluoropyrimidine therapy alone is preferred. Combination chemotherapy has shown a survival benefit compared to 5-FU/LV alone. A survival benefit over 5-FU/LV has not been demonstrated with Xeloda monotherapy. Use of Xeloda instead of 5-FU/LV in combinations has not been adequately studied to assure safety or preservation of the survival advantage.

Breast Cancer

Xeloda in combination with docetaxel is indicated for the treatment of patients with metastatic breast cancer after failure of prior anthracycline-containing chemotherapy.

Xeloda monotherapy is indicated for the 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, e.g., patients who have received cumulative doses of 400 mg/m² of doxorubicin or doxorubicin equivalents. Resistance is defined as progressive disease while on treatment, with or without an initial response, or relapse within 6 months of completing treatment with an anthracycline-containing adjuvant regimen.

IMPORTANT SAFETY INFORMATION

Boxed Warning

Xeloda-Warfarin Interaction

Patients receiving concomitant capecitabine and oral coumarin-derivative anticoagulant therapy should have their anticoagulant response (INR or prothrombin time) monitored frequently in order to adjust the anticoagulant dose accordingly. A clinically important Xeloda-warfarin drug interaction was demonstrated in a clinical pharmacology trial. Altered coagulation parameters and/or bleeding, including death, have been reported in patients taking Xeloda concomitantly with coumarin-derivative anticoagulants such as warfarin and phenprocoumon. Postmarketing reports have shown clinically significant increases in prothrombin time (PT) and INR in patients who were stabilized on anticoagulants at the time Xeloda was introduced. These events occurred within several days and up to several months after initiating Xeloda therapy and, in a few cases, within 1 month after stopping Xeloda. These events occurred in patients with and without liver metastases. Age greater than 60 and a diagnosis of cancer independently predispose patients to an increased risk of coagulopathy.

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IMPORTANT SAFETY INFORMATION (cont)

Contraindications

Severe Renal Impairment

Xeloda is contraindicated in patients with severe renal impairment (creatinine clearance below 30 mL/min [Cockcroft and Gault]).

Hypersensitivity

Xeloda is contraindicated in patients with known hypersensitivity to capecitabine or to any of its components or to 5-fluorouracil.

Warnings and Precautions

Coagulopathy: May result in bleeding, death. Monitor anticoagulant response (e.g., INR) and adjust anticoagulant dose accordingly.

Diarrhea: May be severe. Interrupt Xeloda treatment immediately until diarrhea resolves or decreases to grade 1. Recommend standard antidiarrheal treatments.

Cardiotoxicity: Common in patients with a prior history of coronary artery disease.

Increased risk of severe or fatal adverse reactions in patients with low or absent Dihydropyrimidine Dehydrogenase Deficiency (DPD) activity: Withhold or permanently discontinue Xeloda in patients with evidence of acute early-onset or unusually severe toxicity, which may indicate near complete or total absence of DPD activity. No Xeloda dose has been proven safe in patients with absent DPD activity.

Dehydration and Renal Failure: Interrupt Xeloda treatment until dehydration is corrected. Potential risk of acute renal failure secondary to dehydration. Monitor and correct dehydration.

Embryo-Fetal Toxicity: Can cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus and to use effective contraception.

Mucocutaneous and Dermatologic Toxicity: Severe mucocutaneous reactions, such as Steven-Johnson Syndrome (SJS) and Toxic Epidermal Necrolysis (TEN), have been reported. Xeloda should be permanently discontinued in patients who experience a severe mucocutaneous reaction during treatment. Xeloda may induce hand-and-foot syndrome. Persistent or severe hand-and-foot syndrome can lead to loss of fingerprints which could impact patient identification. Interrupt Xeloda treatment until the hand-and-foot syndrome event resolves or decreases in intensity.

Hyperbilirubinemia: Interrupt Xeloda treatment immediately until the hyperbilirubinemia resolves or decreases in intensity.

Hematologic: Do not treat patients with neutrophil counts $<1.5 \times 10^9/L$ or thrombocyte counts $<100 \times 10^9/L$. If grade 3-4 neutropenia or thrombocytopenia occurs, stop therapy until condition resolves.

Adverse Reactions

The most common adverse reactions ($\geq 30\%$) with Xeloda were diarrhea, hand-and-foot syndrome, nausea, vomiting, abdominal pain, fatigue/weakness, and hyperbilirubinemia. Other adverse reactions, including serious adverse reactions, have been reported.

Use in Specific Populations

Pregnancy

Based on findings in animal reproduction studies and its mechanism of action, Xeloda can cause fetal harm when administered to a pregnant woman. Limited available human data are not sufficient to inform the drug-associated risk during pregnancy. Apprise pregnant women of the potential risk to a fetus.

Lactation

Advise females not to breastfeed during treatment with Xeloda and for 2 weeks after the last dose.

Females and Males of Reproductive Potential

Pregnancy testing

Pregnancy testing is recommended for females of reproductive potential prior to initiating Xeloda.

Contraception

Females

Xeloda can cause fetal harm when administered to a pregnant woman. Advise females of reproductive potential to use effective contraception during treatment and for 6 months following the final dose of Xeloda.

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IMPORTANT SAFETY INFORMATION (cont)

Males

Advise male patients with female partners of reproductive potential to use effective contraception during treatment and for 3 months following the last dose of Xeloda.

Infertility

Based on animal studies, Xeloda may impair fertility in females and males of reproductive potential.

Pediatric Use

The safety and effectiveness of Xeloda in pediatric patients have not been established.

Geriatric Use

Physicians should pay particular attention to monitoring the adverse effects of Xeloda in the elderly.

Hepatic Insufficiency

Exercise caution when patients with mild to moderate hepatic dysfunction due to liver metastases are treated with Xeloda. The effect of severe hepatic dysfunction on Xeloda is not known.

Renal Insufficiency

Patients with moderate (creatinine clearance = 30 to 50 mL/min) and severe (creatinine clearance <30 mL/min) renal impairment showed higher exposure to capecitabine, 5-DFUR, and FBAL than in those with normal renal function.

Please see full [Prescribing Information](#) for additional important safety information.

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