

Xeloda (capecitabine)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Xeloda (capecitabine)

APPROVAL CRITERIA

Requests for Xeloda (capecitabine) may be approved if the following criteria are met:

- I. Colon, Rectal or Anal Carcinoma (NCCN 1, NCCN 2A);

OR

- II. Breast cancer, metastatic or recurrent (Label, NCCN 1, NCCN 2A);

OR

- III. Individual has a diagnosis of brain metastases (NCCN 1, NCCN 2A); **AND**

- IV. Individual has a primary diagnosis of breast cancer; **AND**

- V. Individual is using Xeloda in one of the following ways:

- A. In combination with either lapatinib or neratinib in HER2 positive breast cancer; **OR**
B. In combination with trastuzumab and tucatinib if previously treated with one or more anti-HER2 based regimens; **OR**
C. As single agent therapy for limited or extensive brain metastases;

OR

- VI. Head and Neck Cancers, advanced, recurrent, persistent (NCCN 2A); **AND**
A. Individual is using as a single agent;

OR

- VII. Esophageal and Esophagogastric Cancers (NCCN 1, NCCN 2A);

OR

- VIII. Gastric Cancer (NCCN 1, NCCN 2A);

OR

- IX. Recurrent or progressive Gestational Trophoblastic Neoplasia (NCCN 2A); **AND**
A. Individual is using as a single agent;

OR

- X. Biliary Tract Cancers (NCCN 1, NCCN 2A);
A. Cholangiocarcinoma; **OR**
B. Gallbladder Cancer;

OR

- XI. Neuroendocrine Tumors (NETs) (NCCN 2A);
- A. Extrapulmonary Poorly Differentiated Neuroendocrine Carcinoma/Large or Small Cell Carcinoma/Mixed Neuroendocrine-Non-Neuroendocrine Neoplasm; **OR**
 - B. Gastrointestinal tract, Lung, or Thymus; **OR**
 - C. Pancreas; **OR**
 - D. Poorly Differentiated/Large or Small Cell; **OR**
 - E. Well Differentiated, Grade 3 NETs;

OR

- XII. Occult Primary (NCCN 2A);

OR

- XIII. Ovarian Cancer (NCCN 2A);

OR

- XIV. Pancreatic Adenocarcinoma (NCCN1, NCCN 2A); **AND**
- A. Individual has a current ECOG performance score of 0-2;

OR

- XV. Penile Cancer (NCCN 2A); **AND**
- A. Individual is using as a single agent;

OR

- XVI. Advanced or metastatic Small Bowel Adenocarcinoma, including ampullary adenocarcinoma (NCCN 2A); **AND**
- A. Individual is using as initial therapy; **OR**
 - B. Individual is using as neoadjuvant or adjuvant therapy;

OR

- XVII. Individual has Squamous Cell Skin Cancer (NCCN 2A); **AND**
- A. Individual's disease is locally advanced, high-risk, or very high-risk disease in which curative surgery and curative radiation therapy are not feasible; **AND**
 - B. Individual is ineligible for or progressed on immune checkpoint inhibitors and clinical trials; **AND**
 - C. Individual is using as a single agent treatment;

OR

- XVIII. Thymomas and Thymic Carcinomas; **AND**
- A. Individual is using in combination with gemcitabine.

Requests for **brand** Xeloda must also meet the following criteria, in addition to the above Prior Authorization criteria:

- I. Individual has been receiving and is stabilized on brand Xeloda;

OR

- II. Individual has failed an adequate trial (medication samples/coupons/discount cards are excluded from consideration as a trial) of one chemically equivalent generic capecitabine agent;
- III. excluded from consideration as a trial) of one chemically equivalent generic capecitabine agent;

AND

- A. Generic capecitabine had inadequate response; **OR**
- B. Generic capecitabine caused adverse outcome; **OR**
- C. The individual has a genuine allergic reaction to an inactive ingredient in generic agent. Allergic reaction(s) must be clearly documented in the individual's medical record.

Note:

Xeloda (capecitabine) has a black box warning regarding concomitant use with coumarin-derivative anticoagulants. Concomitant use can alter coagulation parameters that can result in death. Predisposing factors include age greater than 60 and diagnosis of cancer. Individuals should have their INR or prothrombin time monitored frequently to have the dose adjusted accordingly.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2023. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: July 11, 2023.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2023 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on July 11, 2023.
 - a. Ampullary adenocarcinoma. V1.2023. Revised April 27, 2023
 - b. Anal Carcinoma. V2.2023. Revised April 28, 2023.
 - c. Biliary Tract Cancers. V2.2023. Revised May 10, 2023.
 - d. Breast Cancer. V4.2023. Revised March 23, 2023.
 - e. Central Nervous System Cancers. V1.2023. Revised March 24, 2023.
 - f. Colon Cancer. V2.2023. Revised April 25, 2023.
 - g. Esophageal and Esophagogastric Junction Cancers. V2.2023. Revised March 10, 2023.
 - h. Gastric Cancer. V1.2023. Revised March 10, 2023.
 - i. Gestational Trophoblastic Neoplasia. V1.2023. Revised December 20, 2022.
 - j. Head and Neck Cancers. V2.2023. Revised May 15, 2023.
 - k. Neuroendocrine and Adrenal Tumors. V2.2022. Revised December 21, 2022.
 - l. Occult Primary. V3.2023. Revised December 21, 2022.
 - m. Ovarian Cancer. V2.2023. Revised June 2, 2023.
 - n. Pancreatic Adenocarcinoma. V2.2023. Revised June 19, 2023.
 - o. Penile Cancer. V1.2023. Revised December 1, 2022.
 - p. Rectal Cancer. V3.2023. Revised May 26, 2023.
 - q. Small Bowel Adenocarcinoma. V1.2023. Revised January 9, 2023.
 - r. Squamous Cell Skin Cancer. V1.2023. Revised March 10, 2023.
 - s. Thymomas and Thymic Carcinomas. V1.2023. Revised December 15, 2022..
6. Sutherland S, Ashley S, Miles D, et.al. Treatment of HER2-positive metastatic breast cancer with lapatinib and capecitabine in the lapatinib expanded access programme, including efficacy in brain metastases- the UK experience. Br J Cancer. 2010 Mar 16; 102(6): 995-1002. Accessed on July 11, 2021.

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