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, 2A);

OR

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

OR

III. Cervical Cancer (NCCN 1, 2A);

OR

IV. Individual has a diagnosis of brain metastases (NCCN 1, 2A); **AND**
V. Individual has a primary diagnosis of breast cancer; **AND**
VI. 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

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

OR

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

OR

IX. Gastric Cancer (NCCN 1, 2A);

OR

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

OR

XI. Biliary Tract Cancers (NCCN 1, 2A);

A. Cholangiocarcinoma; **OR**
B. Gallbladder Cancer;

OR

XII. 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

XIII. Occult Primary (NCCN 2A);

OR

XIV. Ovarian Cancer (NCCN 2A);

OR

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

OR

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

OR

XVII. 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

XVIII. 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

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

OR

XX. Uterine Neoplasms, excluding adjuvant therapy for stage IB or II disease (NCCN 2A);

OR

XXI. Vaginal or Vulvar Cancer (NCCN 2A).

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

I. Individual has failed an adequate trial of one chemically equivalent generic capecitabine agent. Medication samples/coupons/discount cards are excluded from consideration as a trial.;
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.: 2024. 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 8, 2024.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2024; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2024 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on July 8, 2024.
   a. Ampullary Adenocarcinoma. V1.2024. Revised December 13, 2023
   b. Anal Carcinoma. V1.2024. Revised December 20, 2023.
   c. Biliary Tract Cancers. V2.2024. Revised April 19, 2024.
   d. Breast Cancer. V4.2024. Revised July 3, 2024.
   e. Central Nervous System Cancers. V1.2024. Revised May 31, 2024.
   f. Cervical Cancer.V3.2024. Revised July 3, 2024.
   g. Colon Cancer. V4.2024. Revised April 25, 2023.
   h. Esophageal and Esophagogastric Junction Cancers. V3.2024. Revised April 26, 2024.
   i. Gastric Cancer. V2.2024. Revised May 29, 2024.
   j. Gestational Trophoblastic Neoplasia. V1.2024. Revised October 27, 2023.
   k. Head and Neck Cancers. V4. 2024. Revised May 1, 2024.
   l. Neuroendocrine and Adrenal Tumors. V1. 2024. Revised June 20, 2024.
   m. Occult Primary. V2.2024. Revised April 29, 2024.
   n. Ovarian Cancer. V2.2024. Revised May 13, 2024.
   o. Pancreatic Adenocarcinoma. V2.2024. Revised April 30, 2024.
   p. Penile Caner. V1.2024. Revised October 25, 2023.
   q. Rectal Cancer. V3.2024. Revised July 3, 2024.
   r. Small Bowel Adenocarcinoma. V4.2024. Revised July 3, 2024.
   s. Squamous Cell Skin Cancer. V1.2024. Revised November 9, 2024.
   t. Thymomas and Thymic Carcinomas. V1.2024. Revised November 21, 2023.

u. Uterine Cancer. V2.2024. Revised March 6, 2024.
v. Vaginal Cancer.V1.2025. Revised March 26, 2024.
w. Vulvar Cancer.V4.2024. Revised May 1, 2024.
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.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.