

# 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. Individual is under 19 years of age:

**OR**

II. Ampullary adenocarcinoma (NCCN 2A); **OR**

**OR**

III. Appendiceal Neoplasms and Cancers (NCCN 2A); **OR**

**OR**

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

**OR**

V. Breast cancer, locally advanced, metastatic or recurrent (Label, NCCN 1, 2A);

**OR**

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

**OR**

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

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

IX. 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 (or trastuzumab biosimilars) 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**

X. Head and Neck Cancers, advanced, recurrent, persistent (NCCN 2A); **AND**

A. Individual is using as a single agent;

**OR**

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

**OR**

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

**OR**

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

**OR**

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

**OR**

XV. 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**

XVI. Occult Primary (NCCN 2A);

**OR**

XVII. Ovarian Cancer (NCCN 2A);

**OR**

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

**OR**

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

**OR**

XX. Advanced or metastatic Small Bowel Adenocarcinoma (NCCN 2A);

**OR**

XXI. Individual has Squamous Cell Skin Cancer (NCCN 2A); **AND**  
A. Individual is using in one of the following ways:  
1. Individual is using as treatment for severe refractory field cancerization/confluent epidermal dysplasia that has progressed on oral retinoids; **OR**  
2. Individual's disease is locally advanced, high-risk, or very high-risk disease in which curative surgery and curative radiation therapy are not feasible; **OR**  
3. Individual is ineligible for or progressed on immune checkpoint inhibitors and clinical trials;

**AND**

B. Individual is using as a single agent treatment;

**OR**

XXII. Thymomas and Thymic Carcinomas; **AND**

A. Individual is using in combination with gemcitabine;

**OR**

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

**Key References:**

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: July 1, 2025.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2025; Updated periodically.
4. NCCN Clinical Practice Guidelines in Oncology™. © 2025 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on July 1, 2025.
  - a. Ampullary Adenocarcinoma. V2.2025. Revised January 10, 2025.
  - b. Anal Carcinoma. V4.2025. Revised May 30, 2025.
  - c. Biliary Tract Cancers. V1.2025. Revised March 20, 2025.
  - d. Breast Cancer. V4.2025. Revised April 17, 2025.
  - e. Central Nervous System Cancers. V1.2025. Revised June 3, 2025.
  - f. Cervical Cancer.V4.2025. Revised July 3, 2024.
  - g. Colon Cancer. V4.2024. Revised March 24, 2025.
  - h. Esophageal and Esophagogastric Junction Cancers. V3.2025. Revised April 22, 2025.
  - i. Gastric Cancer. V2.2025. Revised April 4, 2025.
  - j. Gestational Trophoblastic Neoplasia. V3.2025. Revised May 28, 2025.
  - k. Head and Neck Cancers V4.2025. Revised June 20, 2025.
  - l. Neuroendocrine and Adrenal Tumors. V2. 2025. Revised May 28, 2025.
  - m. Occult Primary. V2.2025. Revised September 11, 2024.
  - n. Ovarian Cancer. V2.2025. Revised May 23, 2025.
  - o. Pancreatic Adenocarcinoma. V2.2025. Revised April 30, 2024.
  - p. Penile Cancer. V2.2025. Revised January 6, 2025.
  - q. Rectal Cancer. V2.2025. Revised March 31, 2025.
  - r. Small Bowel Adenocarcinoma. V3.2025. Revised March 31, 2025.
  - s. Squamous Cell Skin Cancer. V2.2025. Revised February 7, 2025.
  - t. Thymomas and Thymic Carcinomas. V2.2025. Revised May 19, 2025.
  - u. Vaginal Cancer.V5.2025. Revised February 28, 2025.
  - v. Vulvar Cancer.V1.2025. Revised February 10, 2025.
5. 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 policies may take precedence over the application of this clinical criteria.

No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from the health plan.