



Federal Employee Program.

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Section:	Prescription Drugs	Effective Date:	January 1, 2026
Subsection:	Antineoplastic Agents	Original Policy Date:	January 1, 2021
Subject:	Xeloda	Page:	1 of 3

Last Review Date: December 12, 2025

Xeloda

Description

Xeloda (capecitabine)

Background

Xeloda (capecitabine) is a nucleoside metabolic inhibitor with antineoplastic activity. Enzymes convert capecitabine to 5-fluorouracil (5-FU) in vivo. Both normal and tumor cells metabolize 5-FU to 5-fluoro-2'-deoxyuridine monophosphate (FdUMP) and 5-fluorouridine triphosphate (FUTP). These metabolites cause cell injury which results in the inhibition of a precursor for DNA synthesis and also interferes with RNA processing and protein synthesis (1).

Regulatory Status

FDA-approved indications: Xeloda is indicated for: (1)

- Colon cancer
- Rectal cancer
- Colorectal cancer
- Breast cancer
- Gastric, esophageal, or gastroesophageal junction cancer
- Pancreatic cancer

Related policies

Policy

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This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Xeloda may be considered **medically necessary** if the conditions indicated below are met.

Xeloda may be considered **investigational** for all other indications.

Prior-Approval Requirements

Diagnoses

Patient must have **ONE** of the following:

1. Colon cancer
2. Rectal cancer
3. Colorectal cancer
4. Breast cancer
5. Gastric, esophageal, or gastroesophageal junction cancer
6. Pancreatic cancer

AND the following for **ALL** indications:

- a. Inadequate treatment response, intolerance, or contraindication to generic Xeloda: capecitabine

Prior – Approval Renewal Requirements

Same as above

Policy Guidelines

Prior - Approval Limits

Duration 12 months

Prior – Approval Renewal Limits

Same as above

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Rationale

Summary

Xeloda (capecitabine) is a nucleoside metabolic inhibitor with antineoplastic activity. Enzymes convert capecitabine to 5-fluorouracil (5-FU) in vivo. Both normal and tumor cells metabolize 5-FU to 5-fluoro-2'-deoxyuridine monophosphate (FdUMP) and 5-fluorouridine triphosphate (FUTP). These metabolites cause cell injury which results in the inhibition of a precursor for DNA synthesis and also interferes with RNA processing and protein synthesis (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Xeloda while maintaining optimal therapeutic outcomes.

References

1. Xeloda [package insert]. South San Francisco, CA: Genentech, Inc.; December 2022.
2. NCCN Drugs & Biologics Compendium® Capecitabine 2025. National Comprehensive Cancer Network, Inc. Accessed on November 11, 2025.

Policy History

Date	Action
December 2020	Addition to PA. Annual review
June 2021	Annual review and reference update
September 2022	Annual review and reference update
January 2023	Per PI update, addition of indications: rectal cancer; gastric, esophageal, or gastoesophageal junction cancer; and pancreatic cancer
March 2023	Annual review and reference update
June 2023	Annual review and reference update
March 2024	Annual review and reference update
June 2024	Annual review and reference update
March 2025	Annual review and reference update
June 2025	Annual review and reference update
December 2025	Annual review and reference update. Removed MedEx requirement and switched to t/f

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 12, 2025 and is effective on January 1, 2026.