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Section:	Prescription Drugs	**Effective Date:**	April 1, 2025
Subsection:	Antineoplastic Agents	**Original Policy Date:**	January 1, 2021
Subject:	Xeloda	**Page:**	1 of 3

Last Review Date: March 7, 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

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** diagnoses:

a. Patient **MUST** have tried the preferred product (generic Xeloda: capecitabine) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

Prior – Approval *Renewal* Requirements

Same as above

Policy Guidelines

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

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 January 8, 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 gastroesophageal 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

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 7, 2025 and is effective on April 1, 2025.