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<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	July 1, 2024
<b>Subsection:</b>	Antineoplastic Agents	<b>Original Policy Date:</b>	January 1, 2021
<b>Subject:</b>	Xeloda	<b>Page:</b>	1 of 3

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**Last Review Date:** June 13, 2024

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## Xeloda

### Description

#### Xeloda (capecitabine)

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#### 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

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#### 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** 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)

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## Prior – Approval *Renewal* Requirements

Same as above

### [Policy Guidelines](#)

### Prior - Approval Limits

**Duration** 12 months

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### 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<sup>®</sup> Capecitabine 2024. National Comprehensive Cancer Network, Inc. Accessed on April 30, 2024.

## 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

## Keywords

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**This policy was approved by the FEP<sup>®</sup> Pharmacy and Medical Policy Committee on June 13, 2024 and is effective on July 1, 2024.**