



XELODA (capecitabine)

RATIONALE FOR INCLUSION IN PA PROGRAM

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

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.