PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Capecitabine Prior Authorization
- Xeloda® (capecitabine tablets – Genentech, generic)

REVIEW DATE: 06/19/2024

OVERVIEW

Capecitabine, a nucleoside metabolic inhibitor with antineoplastic activity, is indicated for the following uses:[1]

- **Breast cancer,** treatment of advanced or metastatic disease:
  - In combination with docetaxel after disease progression on prior anthracycline-containing chemotherapy.
  - As a single agent if an anthracycline- or taxane-containing chemotherapy is not indicated.
- **Colorectal cancer**:
  - Adjuvant treatment of patients with Stage III colon cancer as a single agent or as a component of a combination chemotherapy regimen.
  - Perioperative treatment of locally advanced rectal cancer as a component of chemoradiotherapy in adults.
  - Treatment of patients with unresectable or metastatic colorectal cancer as a single agent or as a component of a combination chemotherapy regimen.
- **Gastric, esophageal, or gastroesophageal junction cancer,** treatment of adults with:
  - Unresectable or metastatic disease as a component of a combination chemotherapy regimen.
  - HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma who have not received prior treatment for metastatic disease as a component of a combination regimen.
- **Pancreatic Cancer,** adjuvant treatment of pancreatic adenocarcinoma as a component of a combination chemotherapy regimen in adults.

Guidelines

The National Comprehensive Cancer Network (NCCN) Compendium recommends use of capecitabine for the indications listed in the FDA-Approved Indications and Other Uses with Supportive Evidence sections.[2]

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of capecitabine. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of capecitabine is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. **Breast Cancer.** Approve for 1 year if the patient is ≥ 18 years of age.

2. **Colon Cancer.** Approve for 1 year if the patient is ≥ 18 years of age.

3. **Esophageal and Esophagogastric Junction Cancers.** Approve for 1 year if the patient is ≥ 18 years of age.

4. **Gastric Cancer.** Approve for 1 year if the patient is ≥ 18 years of age.

5. **Pancreatic Adenocarcinoma.** Approve for 1 year if the patient is ≥ 18 years of age.

Other Uses with Supportive Evidence

6. **Ampullary Adenocarcinoma.** Approve for 1 year if the patient is ≥ 18 years of age.

7. **Anal Carcinoma.** Approve for 1 year if the patient is ≥ 18 years of age.

8. **Biliary Tract Cancer.** Approve for 1 year if the patient is ≥ 18 years of age.

9. **Central Nervous System Cancers.** Approve for 1 year if the patient is ≥ 18 years of age.

10. **Cervical Cancer**. Approve for 1 year if the patient is ≥ 18 years of age.

11. **Endometrial Carcinoma**. Approve for 1 year if the patient is ≥ 18 years of age.

12. **Gestational Trophoblastic Neoplasia.** Approve for 1 year if the patient is ≥ 18 years of age.

13. **Head and Neck Cancers.** Approve for 1 year if the patient is ≥ 18 years of age.

14. **Neuroendocrine and Adrenal Tumors.** Approve for 1 year if the patient is ≥ 18 years of age.

15. **Occult Primary Tumors.** Approve for 1 year if the patient is ≥ 18 years of age.

16. **Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer.** Approve for 1 year if the patient is ≥ 18 years of age.

17. **Penile Cancer.** Approve for 1 year if the patient is ≥ 18 years of age.

18. **Rectal Cancer.** Approve for 1 year if the patient is ≥ 18 years of age.

19. **Small Bowel Adenocarcinoma.** Approve for 1 year if the patient is ≥ 18 years of age.

20. **Squamous Cell Skin Cancer.** Approve for 1 year if the patient is ≥ 18 years of age.

21. **Thymomas and Thymic Carcinomas.** Approve for 1 year if the patient is ≥ 18 years of age.

22. **Vaginal Cancer.** Approve for 1 year if the patient is ≥ 18 years of age.

23. **Vulvar Cancer**. Approve for 1 year if the patient is ≥ 18 years of age.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of capecitabine is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Xeloda® tablets [prescribing information]. South San Francisco, CA: Genentech; December 2022.
2. The NCCN Drugs & Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on June 17, 2024. Search terms: capecitabine.