VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 07/27/2022; selected revision 09/14/2022

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 adults with locally advanced rectal cancer as a component of chemoradiotherapy.
  - 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 adults with pancreatic adenocarcinoma as a component of a combination chemotherapy regimen.

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

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

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

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

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

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

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

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

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

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

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

19. **Thymomas and Thymic Carcinomas.** 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. © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on July 25, 2022. Search terms: capecitabine.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	07/14/2021
Selected Revision	For all approval conditions, the approval duration was changed from 3 years to 1 year.	06/22/2022
Annual Revision	The title of the policy changed to add "with Step Therapy." **Ampullary Adenocarcinoma:** Condition of approval and criteria were added.	07/27/2022
Selected Revision	The name of the policy was changed from Oncology – Capecitabine PA with Step Therapy to Oncology – Capecitabine PA. For all approval conditions, the requirement for trial of generic capecitabine and the criterion that the patient cannot take generic capecitabine due to a formulation difference in the inactive ingredient between the brand and bioequivalent generic product, which, per the prescriber, would results in a significant allergy or serious adverse reaction was removed. The documentation requirement was also removed. For all approval conditions, the requirement that the patient is ≥ 18 years old was added.	09/14/2022
Update	**12/20/2022**: The overview section was updated to include new FDA approved indications of gastric, esophageal, or gastroesophageal junction cancer and of pancreatic cancer; breast and colorectal indications were also modified as per updated labeling. The following indications were moved from the Other Uses with Supportive Evidence into FDA approved indications section: Esophageal and Esophagogastric Junction Cancers, Gastric Cancer, and Pancreatic Adenocarcinoma.	--