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:

- **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.

**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.
### HISTORY

<table>
<thead>
<tr>
<th>Type of Revision</th>
<th>Summary of Changes</th>
<th>Review Date</th>
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<tbody>
<tr>
<td>New Policy</td>
<td>--</td>
<td>07/14/2021</td>
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<tr>
<td>Selected Revision</td>
<td>For all approval conditions, the approval duration was changed from 3 years to 1 year.</td>
<td>06/22/2022</td>
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<tr>
<td>Annual Revision</td>
<td>The title of the policy changed to add “with Step Therapy.” \n<strong>Ampullary Adenocarcinoma:</strong> Condition of approval and criteria were added.</td>
<td>07/27/2022</td>
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<tr>
<td>Selected Revision</td>
<td>The name of the policy was changed from Oncology – Capecitabine PA with Step Therapy to Oncology – Capecitabine PA. \nFor 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 result in a significant allergy or serious adverse reaction was removed. The documentation requirement was also removed. \nFor all approval conditions, the requirement that the patient is ≥ 18 years old was added.</td>
<td>09/14/2022</td>
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<tr>
<td>Update</td>
<td>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.</td>
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