PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 08/23/2023

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

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.

Xeloda® (capecitabine tablets (Genentech, generic) is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

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. **Biliary Tract Cancer.** 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 Tumors.** 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 COVERED

**Xeloda® (capecitabine tablets (Genentech, generic)
is(are) considered experimental, investigational, or unproven for ANY other use(s).**

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
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	09/14/2022

	reaction was removed. The documentation requirement was also removed. For all approval conditions, the requirement that the patient is ≥ 18 years old was added.	
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.	--
Annual Revision	**Biliary Tract Cancer:** The condition of approval of "hepatobiliary cancer" was changed to "biliary tract cancer."	08/23/2023