PREFERRED SPECIALTY MANAGEMENT POLICY

POLICY: Oncology – Capecitabine Preferred Specialty Management Policy
- 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.

POLICY STATEMENT

This Preferred Specialty Management program has been developed to encourage the use of the Preferred Product. For all medications (Preferred and Non-Preferred), the patient is required to meet the standard *Oncology – Capecitabine Prior Authorization Policy* criteria. The program also directs the patient to try the Preferred Product prior to the approval of the Non-Preferred Product. Requests for Non-Preferred Products will also be reviewed using the exception criteria (below). If the patient meets the standard *Oncology – Capecitabine Prior Authorization Policy* criteria but has not tried a Preferred Product, approval for a Preferred Product will be authorized. All approvals are provided for the duration noted below.

Documentation: Documentation will be required where noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes, prescription claims records, and prescription receipts.

Preferred Product: generic capecitabine tablets
Non-Preferred Product: Xeloda

Oncology – Capecitabine non-preferred product(s) is(are) covered as medically necessary when the following non-preferred product exception criteria is(are) met. Any other exception is considered not medically necessary.

NON-PREFERRED PRODUCT EXCEPTION CRITERIA

Non-Preferred Product	Exception Criteria
Xeloda	**1.** Approve for 1 year if the patient meets ALL of the following (A, B, and C): **A)** Patient meets the standard *Oncology – Capecitabine Prior Authorization (PA) Policy* criteria; AND **B)** Patient has tried generic capecitabine tablets; AND **C)** Patient cannot continue to use generic capecitabine tablets due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] which, per the prescriber, would result in a significant allergy or serious adverse reaction **[documentation required]**.

	2. For a patient who has met the *Oncology – Capecitabine PA Policy* criteria, but has not met exception criteria (1B) and/or (1C): approve generic capecitabine tablets for 1 year.

REFERENCES

1. Xeloda® tablets [prescribing information]. South San Francisco, CA: Genentech; December 2022.
2. The NCCN Drugs & Biologics Compendium. © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on August 15, 2023. Search terms: capecitabine.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	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	--
Early Annual Revision	No criteria changes.	08/23/2023