PREFERRED SPECIALTY MANAGEMENT POLICY

POLICY: Oncology – Capecitabine Preferred Specialty Management Policy
- Xeloda® (capecitabine tablets – Genentech, generic)

REVIEW DATE: 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.

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.

Automation: None.

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

RECOMMENDED 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. © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on July 25, 2022. Search terms: capecitabine.