Reference number(s)
1993-A

SPECIALTY GUIDELINE MANAGEMENT

XELODA (capecitabine)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications
1. Colorectal Cancer
   a. Xeloda is indicated as a single agent for adjuvant treatment in patients with Dukes' C colon cancer who have undergone complete resection of the primary tumor when treatment with fluoropyrimidine therapy alone is preferred.
   b. Xeloda is indicated as first-line treatment in patients with metastatic colorectal carcinoma when treatment with fluoropyrimidine therapy alone is preferred.
2. Breast Cancer
   a. Xeloda in combination with docetaxel is indicated for the treatment of patients with metastatic breast cancer after failure of prior anthracycline-containing chemotherapy.
   b. Xeloda monotherapy is also indicated for the treatment of patients with metastatic breast cancer resistant to both paclitaxel and an anthracycline-containing chemotherapy regimen or resistant to paclitaxel and for whom further anthracycline therapy is not indicated, for example, patients who have received cumulative doses of 400 mg/m^2 of doxorubicin or doxorubicin equivalents.

B. Compendial Uses
1. Anal cancer
2. Breast cancer
3. Central nervous system (CNS) metastases from breast cancer
4. Colorectal Cancer
5. Esophageal and esophagogastric junction cancer
6. Gastric cancer
7. Head and neck cancer
8. Hepatobiliary cancers (extra-/intra-hepatic cholangiocarcinoma and gallbladder cancer)
9. Occult primary tumors (cancer of unknown primary)
10. Ovarian cancer (Epithelial ovarian cancer/fallopian tube cancer/primary peritoneal cancer/mucinous cancer)
11. Pancreatic adenocarcinoma
12. Penile cancer
13. Neuroendocrine and adrenal tumors

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

A. Colorectal Cancer (CRC)
Authorization of 12 months may be granted for the treatment of colorectal cancer.

B. Breast Cancer
Authorization of 12 months may be granted for the treatment of recurrent or metastatic breast cancer.

C. Neuroendocrine and Adrenal Tumors
Authorization of 12 months may be granted for the treatment of neuroendocrine and adrenal tumors.

D. Pancreatic Adenocarcinoma
Authorization of 12 months may be granted for the treatment of pancreatic adenocarcinoma.

E. Esophageal and Esophagogastric Junction Cancers
Authorization of 12 months may be granted for the treatment of esophageal and esophagogastric junction cancers.

F. Gastric Cancer
Authorization of 12 months may be granted for the treatment of gastric cancer.

G. Extrahepatic and Intrahepatic Cholangiocarcinoma and Gallbladder Cancer
Authorization of 12 months may be granted for the treatment of extrahepatic and intrahepatic cholangiocarcinoma and gallbladder cancer.

H. Ovarian Cancer
Authorization of 12 months may be granted for the treatment of ANY of the following:
1. Epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer
2. Mucinous carcinoma

I. Head and Neck Cancer
Authorization of 12 months may be granted for the treatment of head and neck cancer.

J. CNS Metastases from Breast Cancer
Authorization of 12 months may be granted for the treatment of CNS metastases from breast cancer.

K. Occult Primary Tumors (cancer of unknown primary)
Authorization of 12 months may be granted for the treatment of occult primary tumors.

L. Penile Cancer
Authorization of 12 months may be granted for the treatment of penile cancer.

M. Anal Cancer
Authorization of 12 months may be granted for the treatment of anal cancer.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet ALL initial authorization criteria.

IV. REFERENCES

1. Xeloda [package insert]. South San Francisco, CA: Genentech, Inc.; March 2015.
2. The NCCN Drugs & Biologics Compendium™ © 2018 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed July 25, 2018.