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 cancers (including very advanced head and neck cancer)
8. Hepatobiliary cancers (including extrahepatic and intra-hepatic cholangiocarcinoma and gallbladder cancer)
9. Occult primary tumors (cancer of unknown primary)
10. Ovarian cancer, fallopian tube cancer, and primary peritoneal cancer: Epithelial ovarian cancer, fallopian tube cancer, primary peritoneal cancer, and mucinous cancer)
11. Pancreatic adenocarcinoma
12. Penile cancer
13. Neuroendocrine and adrenal tumors
14. Thymomas and Thymic Carcinomas
15. Gestational Trophoblastic Neoplasia
16. Small bowel adenocarcinoma

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

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

B. Breast Cancer
Authorization of 12 months may be granted for treatment of breast cancer in members when any of the following criteria are met:
1. Member has human epidermal growth factor receptor 2 (HER2) negative recurrent or metastatic disease, as a single agent or in combination with docetaxel; or
2. Member has human epidermal growth factor receptor 2 (HER2) positive advanced, recurrent, or metastatic disease, in combination with trastuzumab, lapatinib, or neratinib; or
3. Member has human epidermal growth factor receptor 2 (HER2) positive recurrent, advanced unresectable, or metastatic disease, in combination with trastuzumab and tucatinib, when one or more prior anti-HER2-based regimens were received in the metastatic setting; or
4. Xeloda will be used in combination with ixabepilone for treatment of metastatic or locally advanced disease; or
5. Xeloda will be used as adjuvant therapy.

C. Neuroendocrine and Adrenal Tumors
Authorization of 12 months may be granted for treatment of ANY of the following:
1. Member has neuroendocrine and adrenal tumors of the gastrointestinal tract, lung, or thymus (carcinoid tumors); or
2. Member has neuroendocrine and adrenal tumors of the pancreas; or
3. Member has poorly differentiated (high grade)/large or small cell disease, in combination with temozolomide.

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

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

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

G. Hepatobiliary Cancers
Authorization of 12 months may be granted for treatment of hepatobiliary cancers (including extrahepatic and intrahepatic cholangiocarcinoma and gallbladder cancer).

H. Ovarian Cancer, Fallopian Tube Cancer, and Primary Peritoneal Cancer
Authorization of 12 months may be granted for treatment of ANY of the following:
1. Member has persistent or recurrent epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer, as a single agent; or
2. Member has mucinous carcinoma and when either of the following criteria are met:
   a. Xeloda will be used in combination with oxaliplatin as adjuvant treatment; or
   b. Xeloda will be used in combination with oxaliplatin for treatment of persistent or recurrent disease.

I. Head and Neck Cancers
Authorization of 12 months may be granted for treatment of head and neck cancers (including very advanced head and neck cancer), as a single agent.

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

K. Penile Cancer
Authorization of 12 months may be granted for treatment of penile cancer, as a single agent.

L. Anal Cancer
Authorization of 12 months may be granted for treatment of anal cancer with concurrent chemoradiation in combination with mitomycin.

M. Thymomas and Thymic Carcinomas
Authorization of 12 months may be granted for treatment of thymomas and thymic carcinomas, as second-line therapy in combination with gemcitabine.

N. Gestational Trophoblastic Neoplasia
Authorization of 12 months may be granted for treatment of gestational trophoblastic neoplasia.

O. Small Bowel Adenocarcinoma
Authorization of 12 months may be granted for treatment of small bowel adenocarcinoma.

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section II when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

IV. REFERENCES

1. Xeloda [package insert]. South San Francisco, CA: Genentech, Inc.; February 2019.
2. The NCCN Drugs & Biologics Compendium 2020 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed July 9, 2020.
3. Clinical Pharmacology powered by ClinicalKey [database online]. Tampa, FL. Elsevier; https://www.clinicalkey.com/pharmacology/ [available with subscription]. Accessed July 9, 2020.
4. Ixempra [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; January 2016.
5. Nerlynx [package insert]. Los Angeles, CA: Puma Biotechnology; February 2020.
6. Tukysa [package insert]. Seattle Genetics, Inc.: Bothell, WA; April 2020.
7. Lexicomp [database online]. Hudson, OH: Lexi-Comp, Inc.; http://online.lexi.com/lco/action/index/dataset/complete_ashp [available with subscription]. Accessed July 9, 2020.
8. Micromedex Solutions [database online]. Ann Arbor, MI: Truven Health Analytics Inc. Updated periodically. www.micromedexsolutions.com [available with subscription]. Accessed July 9, 2020.
9. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Gestational Trophoblastic Neoplasia. Version 2.2020. https://www.nccn.org/professionals/physician_gls/pdf/gtn.pdf. Accessed July 9, 2020.