SPECIALTY GUIDELINE MANAGEMENT

XELODA® (capecitabine)

POLICY

A. 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.

FDA-Approved Indications

- Colorectal Cancer
  - 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.
  - Xeloda is indicated as first-line treatment in patients with metastatic colorectal carcinoma when treatment with fluoropyrimidine therapy alone is preferred.

- Breast Cancer
  - Xeloda in combination with docetaxel is indicated for the treatment of patients with metastatic breast cancer after failure of prior anthracycline-containing chemotherapy.
  - 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/m² of doxorubicin or doxorubicin equivalents.

Compendial Uses

- Anal cancer
- Central nervous system (CNS) metastases from breast cancer
- Esophageal and esophagogastric junction cancers
- Gastric cancer
- Hepatobiliary cancers (extra-/intra-hepatic cholangiocarcinoma and gallbladder cancer)
- Lung neuroendocrine tumors (LNET)
- Occult primary tumors (cancer of unknown primary)
- Ovarian cancer
- Pancreatic adenocarcinoma
- Pancreatic neuroendocrine tumors (PNET) (islet cell tumors)
- Penile cancer
- Head and neck cancer
- Renal cell carcinoma (RCC)

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

B. CRITERIA FOR APPROVAL

1. Anal cancer
   a. Authorizations of up to 12 months may be granted for members prescribed Xeloda in combination with mitomycin (may be used with radiation; chemoradiation) for the treatment of anal cancer.

2. Breast cancer
   a. Authorizations of up to 12 months may be granted for members prescribed Xeloda for recurrent or metastatic disease who meet ANY of the following criteria:
      i. In combination with docetaxel AND member failed previous anthracycline-containing chemotherapy
      ii. Used as a single agent for disease resistant to both paclitaxel and an anthracycline-based chemotherapy, or resistant to paclitaxel and for who further anthracycline therapy is not indicated
      iii. In combination with docetaxel or as a single agent for human epidermal growth factor receptor (HER)2 negative and hormone receptor negative disease
iv. In combination with docetaxel or as a single agent for HER2 negative and hormone receptor positive disease that is refractory to endocrine therapy
v. In combination with Ixempra, AND the disease is resistant to taxane therapy, AND anthracycline-based chemotherapy or the anthracycline-based chemotherapy is contraindicated
vi. In combination with trastuzumab for HER2 positive and hormone receptor negative disease
vii. In combination with trastuzumab for HER2 positive and hormone receptor positive disease that is refractory to endocrine therapy
viii. In combination with lapatinib or trastuzumab, AND member previously has received trastuzumab, AND the disease is HER2 positive

3. Colorectal cancer (CRC)
   a. Authorizations of up to 12 months may be granted for members prescribed Xeloda as a single agent or in combination with bevacizumab and/or oxaliplatin or radiation therapy for the treatment of CRC.

4. CNS metastases from breast cancer
   a. Authorizations of up to 12 months may be granted for members prescribed Xeloda as a single agent or in combination with lapatinib for recurrent disease.

5. Esophageal, esophagogastric junction, or gastric cancers
   a. Authorizations of up to 12 months may be granted for members prescribed Xeloda who meet ANY of the following criteria:
      i. Used as a single agent, or as a part of modified ECF (epirubicin, cisplatin or oxaliplatin, and capecitabine) regimen, with radiation, or with cisplatin or oxaliplatin (may be used with radiation; chemoradiation)
      ii. In combination with trastuzumab and cisplatin, AND the disease is advanced or metastatic (including palliative), AND the disease is HER2 positive

6. Head and neck cancer
   a. Authorizations of up to 12 months may be granted for members prescribed Xeloda as a single agent.

7. Hepatobiliary cancers (extra-/intra-hepatic cholangiocarcinoma and gallbladder cancer)
   a. Authorizations of up to 12 months may be granted for members prescribed Xeloda as a single agent or in combination with cisplatin, oxaliplatin, gemcitabine, or radiation therapy.

8. Lung neuroendocrine tumors (LNET)
   a. Authorizations of up to 12 months may be granted for members prescribed Xeloda in combination with temozolomide.

9. Occult primary tumors (cancer of unknown primary)
   a. Authorizations of up to 12 months may be granted for members prescribed Xeloda in combination with oxaliplatin (may be used with radiation; chemoradiation).

10. Ovarian cancer (epithelial ovarian cancer/fallopian tube cancer/primary peritoneal cancer)
    a. Authorizations of up to 12 months may be granted for members prescribed Xeloda as a single agent for persistent or recurrent disease.

11. Pancreatic adenocarcinoma
    a. Authorizations of up to 12 months may be granted for members prescribed Xeloda who meet ANY of the following criteria:
       i. Used in combination with gemcitabine or radiation therapy
       ii. Used as a single agent if member has progressive disease AND has received prior gemcitabine-based chemotherapy

12. Pancreatic neuroendocrine tumors (PNET) (islet cell tumors)
13. Penile cancer
   a. Authorizations of up to 12 months may be granted for members prescribed Xeloda as a single agent or
      with radiation therapy for palliative treatment.

14. RCC
   a. Authorizations of up to 12 months may be granted for members prescribed Xeloda in combination with
      gemcitabine.

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

D. DOSAGE AND ADMINISTRATION
Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or
evidence-based practice guidelines.

REFERENCES