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
A. Anal cancer
B. Breast cancer
C. Central nervous system (CNS) metastases from breast cancer
D. Colorectal Cancer
E. Esophageal and esophagogastric junction cancers
F. Gastric cancer
G. Head and neck cancer
H. Hepatobiliary cancers (extra-/intra-hepatic cholangiocarcinoma and gallbladder cancer)
I. Lung neuroendocrine tumors (LNET)
J. Occult primary tumors (cancer of unknown primary)
K. Ovarian cancer
L. Pancreatic adenocarcinoma
M. Pancreatic neuroendocrine tumors (PNET) (islet cell tumors)
N. Penile cancer

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

II. CRITERIA FOR INITIAL APPROVAL

A. Colorectal Cancer (CRC)
1. Authorization of 6 months may be granted for the treatment of resectable disease when Xeloda is used in any of the following settings:
   i. Neoadjuvant therapy
   ii. Adjuvant therapy
   iii. Perioperative therapy

2. Authorization of 12 months may be granted for the treatment of unresectable, advanced or metastatic disease when Xeloda will be used in ONE of the following settings:
   a. Initial therapy
   b. Therapy after first progression (second-line therapy) or second progression (third-line therapy) for disease not previously treated with an oxaliplatin-based regimen.

B. Breast Cancer

Authorization of 12 months may be granted for the treatment of recurrent or metastatic disease when Xeloda is used as a single agent, in combination with docetaxel, trastuzumab, or lapatinib.

C. Pancreatic Adenocarcinoma

1. Authorization of 6 months may be granted for the neoadjuvant or adjuvant treatment of resectable disease when Xeloda is used as chemoradiation.
2. Authorization of 12 months may be granted for the treatment of locally advanced unresectable or metastatic disease.
3. Authorization of 6 months may be granted for treatment following chemotherapy in members with locally advanced unresectable disease when Xeloda is used as chemoradiation.

D. Esophageal and Esophagogastric Junction Cancers

1. Authorization of 6 months may be granted for the treatment of locoregional disease when Xeloda is used as chemoradiation.
2. Authorization of 6 months may be granted for the treatment of locoregional disease when Xeloda is used as perioperative (pre- and/or post-operative) chemotherapy.
3. Authorization of 12 months may be granted for first-line palliative therapy (eg, unresectable/medically inoperable locally advanced, locally recurrent or metastatic disease).

E. Gastric Cancer

1. Authorization of 6 months may be granted for the treatment of locoregional disease when Xeloda is used as primary chemotherapy.
2. Authorization of 6 months may be granted for the treatment of locoregional disease when Xeloda is used as perioperative (pre- and/or post-operative) chemotherapy.
3. Authorization of 6 months may be granted for the treatment of locoregional disease when Xeloda is used as chemoradiation.
4. Authorization of 12 months may be granted for first-line palliative therapy (eg, unresectable/medically inoperable locally advanced, locally recurrent or metastatic disease).

F. Hepatobiliary Cancers (extra-/intra-hepatic cholangiocarcinoma and gallbladder cancer)

1. Authorization of 6 months may be granted for the adjuvant treatment of resected disease.
2. Authorization of 12 months may be granted for the primary treatment of unresectable or metastatic disease.

G. Pancreatic Neuroendocrine Tumors (PNET) (islet cell tumors)

Authorization of 12 months may be granted for the treatment of unresectable or metastatic disease when ALL of the following criteria are met:

a. Xeloda is used in combination with temozolomide
b. The member has symptoms, clinically significant tumor burden, or clinically significant progression.

H. Ovarian Cancer (epithelial ovarian cancer/fallopian tube cancer/primary peritoneal cancer)

Authorization of 12 months may be granted for the treatment of persistent or recurrent disease when Xeloda is used as a single agent.

I. Head and Neck Cancer

Authorization of 12 months may be granted for the treatment of head and neck cancer when Xeloda is used as a single agent.

J. Lung Neuroendocrine Tumors (LNET)
Authorization of 12 months may be granted for the treatment of LNET when Xeloda is used in combination with temozolomide.

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

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

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

N. 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. DOSAGE AND ADMINISTRATION

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

V. REFERENCES

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3. DRUGDEX® System (electronic version). Truven Health Analytics, Ann Arbor, MI. Available at http://www.micromedexsolutions.com [available with subscription]. Accessed August 18, 2016.
4. AHFS Drug Information. http://online.lexi.com/lco. Accessed August 18, 2016.
5. The NCCN Clinical Practice Guidelines in Oncology® Colon cancer (Version 2.2016). © 2016 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed August 11, 2016.
6. The NCCN Clinical Practice Guidelines in Oncology® Rectal cancer (Version 2.2016). © 2016 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed August 11, 2016.
7. The NCCN Clinical Practice Guidelines in Oncology® Breast cancer (Version 2.2016). © 2016 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed August 11, 2016.
8. The NCCN Clinical Practice Guidelines in Oncology® Pancreatic adenocarcinoma (Version 1.2016). © 2016 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed August 11, 2016.
9. The NCCN Clinical Practice Guidelines in Oncology® Esophageal and esophagogastric junction cancers (Version 2.2016). © 2016 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed August 11, 2016.
10. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Gastric Cancer: Version 3.2016. http://www.nccn.org/professionals/physician_gls/pdf/gastric.pdf. Accessed August 11, 2016.