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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/m² of doxorubicin or doxorubicin equivalents.

B. Compendial Uses

1. Anal carcinoma
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, mucinous cancer, carcinosarcoma (malignant mixed Mullerian tumors), clear cell carcinoma, grade 1 endometrioid carcinoma, low-grade serious carcinoma/ovarian borderline epithelial tumor (low malignant potential) with invasive implants
11. Pancreatic adenocarcinoma
12. Penile cancer
13. Neuroendocrine and adrenal tumors
14. Thymomas and Thymic Carcinomas
15. Gestational Trophoblastic Neoplasia
16. Small bowel adenocarcinoma
17. Squamous cell skin cancer

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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 early-stage HER2 negative postoperative residual disease, as a single agent
3. Member has HER2 positive advanced, recurrent, unresectable, or metastatic disease, in combination with a HER2 inhibitor (e.g., margetuximab-cmkb [Margenza], trastuzumab [Herceptin], lapatinib [Tykerb], or neratinib [Nerlynx]), as subsequent therapy; or
4. Member has 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
5. Xeloda will be used in combination with ixabepilone for treatment of metastatic or locally advanced disease; or
6. 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; or
4. Member has well differentiated grade 3 neuroendocrine tumors, in combination with temozolomide or as a component of CAPEOX (capecitabine and oxaliplatin) regimen

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. As a single agent therapy for persistent or recurrent epithelial ovarian cancer, fallopian tube cancer, primary peritoneal cancer, carcinosarcoma (malignant mixed Mullerian tumors), clear cell carcinoma,

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grade 1 endometrioid carcinoma, low-grade serous carcinoma/ovarian borderline epithelial tumor (low malignant potential) with invasive implants; 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 as a single agent or 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 Carcinoma

Authorization of 12 months may be granted for treatment of anal carcinoma when any of the following criteria are met:

1. The requested drug will be used with concurrent chemoradiation in combination with mitomycin.
2. The requested drug will be used with radiation after primary treatment of metastatic disease, as a single agent.

M. Thymomas and Thymic Carcinomas

Authorization of 12 months may be granted for treatment of thymomas and thymic carcinomas 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, including advanced ampullary cancer.

P. Squamous Cell Skin Cancer

Authorization of 12 months may be granted for treatment of squamous cell skin cancer when all of the following criteria are met:

1. Disease is unresectable/inoperable, locally advanced, recurrent, or metastatic
2. Member is ineligible for or has progressed on immune checkpoint inhibitors and clinical trials
3. Xeloda will be used as a single agent.

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.; May 2021.

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3. Clinical Pharmacology powered by ClinicalKey [database online]. Tampa, FL. Elsevier; <https://www.clinicalkey.com/pharmacology/> [available with subscription]. Accessed July 13, 2021.
4. Ixempra [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; January 2016.
5. Nerlynx [package insert]. Los Angeles, CA: Puma Biotechnology, Inc.; June 2021.
6. Tukysa [package insert]. Bothell, WA: Seattle Genetics, Inc.; April 2020.
7. Margenza [package insert]. Rockville, MD: MacroGenics, Inc.; December 2020.
8. Herceptin [package insert]. South San Francisco, CA: Genentech, Inc.; February 2021.
9. Tykerb [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; February 2021
10. Lexicomp [database online]. Hudson, OH: Lexi-Comp, Inc.; http://online.lexi.com/lco/action/index/dataset/complete_ashp [available with subscription]. Accessed July 14, 2021
11. Micromedex Solutions [database online]. Ann Arbor, MI: Truven Health Analytics Inc. Updated periodically. www.micromedexsolutions.com [available with subscription]. Accessed July 14, 2021.
12. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Gestational Trophoblastic Neoplasia. Version 2.2021. https://www.nccn.org/professionals/physician_gls/pdf/gtn.pdf. Accessed July 14, 2021.