MEDICATION POLICY

Generic Name: Capecitabine

Therapeutic Class or Brand Name: Xeloda®

Applicable Drugs (if Therapeutic Class)**:**

Preferred: Capecitabine tablets (generic)

Non-Preferred: Xeloda® tablets

Date of Origin: 2/1/13 **Date Last Reviewed/Revised:** 12/5/17

GPI Code: 2130000500

Prior Authorization Criteria (may be considered medically necessary when criteria I through IV are met):

I. Documented diagnosis of one of the following conditions A through F AND must meet criteria listed under applicable diagnosis:

A. Duke's Stage C colon cancer that has undergone complete resection of the primary tumor.

B. Metastatic colorectal carcinoma.

C. Recurrent or metastatic breast cancer when criterion 1 or 2 is met:

1. As monotherapy in patients when criterion a or b is met:

a. Contraindication or failure to both paclitaxel and an anthracycline-containing chemotherapy regimen.

b. Contraindication or failure to paclitaxel and for whom further anthracycline therapy is not indicated (i.e. patients who have received cumulative doses of 400 mg/m^2 of doxorubicin or doxorubicin equivalents).

2. As combination therapy in conjunction with docetaxel in patients with a contraindication or failure on an anthracycline containing chemotherapy.

D. Advanced or metastatic HER2 positive breast cancer AND criteria 1 and 2 are met:

1. Must be used in combination with Tykerb®.

2. Documentation of prior therapy, including the following 3 agents listed a through c:

a. An anthracycline (i.e. daunorubicin, doxorubicin, epirubicin, idarubicin, valrubicin).

b. A taxane (i.e. paclitaxel, docetaxel).

c. Herceptin®.

E. Pancreatic adenocarcinoma.

F. Advanced gastro-esophageal cancer.

II. Minimum age requirement: 18 years old.

III. The prescribing physician is an oncologist or a hematologist.

IV. Non-preferred products (i.e. Xeloda® tablets) require a documented clinical reason containing details as to why generic capecitabine is not appropriate or is contraindicated.

Exclusion Criteria:

- Patients with dihydropyrimidine dehydrogenase (DPD) deficiency.
- Patients with severe renal impairment (creatinine clearance below 30 mL/min).

Other Criteria:

- N/A

Quantity/Days Supply Restrictions:

- The quantity is limited to a maximum of a 30 day supply per fill.

Approval Length:

- **Authorization:**
  - Duke's Stage C colon cancer: One time for a total of 24 weeks.
  - All other Covered Uses: 1 year.
- **Re-Authorization:**
  - Duke's Stage C colon cancer: N/A
  - All other Covered Uses: An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective.

Appendix:

N/A

References:

1. Medi-Span.
2. http://www.gene.com/download/pdf/xeloda_prescribing.pdf.

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3. https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/tykerb.pdf.

MEDICATION POLICY

Historical Tracking Of Changes Made To Policy	
12/5/2017	1. **Changed** "N/A" **to** "Preferred: Capecitabine tablets (generic); Non-Preferred: Xeloda® tablets" **under Applicable Drugs**. 2. **Added** "IV. Non-preferred products (i.e. Xeloda® tablets) require a documented clinical reason containing details as to why generic capecitabine is not appropriate or is contraindicated" **under Prior Authorization Criteria**. 3. **Removed** "https://www.optumrx.com/rxsol/live/PAGDocs/Guideline_2709.pdf" **and** "https://www.optumrx.com/rxsol/live/PAGDocs/Guideline_7297.pdf" **under References** (links no longer valid).
9/24/2016	1. **Changed** "I. Documented diagnosis of one of the following conditions A through E…" **to** "I. Documented diagnosis of one of the following conditions A through F…" **under Prior Authorization Criteria**. 2. **Added** "I. D. Advanced or metastatic HER2 positive breast cancer AND criteria 1 and 2 are met: 1. Must be used in combination with Tykerb®; 2. Documentation of prior therapy, including the following 3 agents listed a through c: a. An anthracycline (i.e. daunorubicin, doxorubicin, epirubicin, idarubicin, valrubicin); b. A taxane (i.e. paclitaxel, docetaxel); c. Herceptin®" **to Prior Authorization Criteria**. 3. **Removed** "http://www.connecticare.com/provider/PDFs/Pharmacy/Xeloda.pdf" **under References** (link no longer valid). 4. **Added** "https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/tykerb.pdf" **under References**.
3/24/2015	1. Policy reviewed: no changes made.
11/13/2013	1. **Adapted policy to new format.** 2. **Added GPI code**. 3. **Added** "Patients with dihydropyrimidine dehydrogenase (DPD) deficiency; Patients with severe renal impairment (creatinine clearance below 30 mL/min)" **under Exclusion Criteria**. 4. **Updated references** to include Medi-Span.