



MEDICATION POLICY

Generic Name: Capecitabine

Therapeutic Class or Brand Name: Xeloda®

Applicable Drugs (if Therapeutic Class): N/A

Date of Origin: 2/1/13

Date Last Reviewed/Revised: 9/24/16

GPI Code: 2130000500

Prior Authorization Criteria (may be considered medically necessary when criteria I through III 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/m² 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.

Disclaimer: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgment in providing the most appropriate care for their patients.



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

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. https://www.optumrx.com/rxsol/live/PAGDocs/Guideline_2709.pdf.
2. https://www.optumrx.com/rxsol/live/PAGDocs/Guideline_7297.pdf.
3. [Medi-Span](#).
4. http://www.gene.com/download/pdf/xeloda_prescribing.pdf.
5. <https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/tykerb.pdf>.

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Historical Tracking Of Changes Made To Policy	
9/24/2016	<ol style="list-style-type: none">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	<ol style="list-style-type: none">1. Policy reviewed: no changes made.
11/13/2013	<ol style="list-style-type: none">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.

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