STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CAPECITABINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CAPECITABINE	XELODA, CAPECITABINE	18385		GPI-10 (2130000500)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Stage III colon cancer **AND** meet the following criterion?
   - The requested medication will be used as adjuvant treatment

   If yes, **approve for 12 months by HICL or GPI-10 for 8 fills.**
   If no, continue to #2.

2. Does the patient have a diagnosis of locally advanced rectal cancer and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The requested medication will be used as perioperative treatment
   - The requested medication will be used as part of chemoradiotherapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #3.

3. Does the patient have a diagnosis of unresectable or metastatic colorectal cancer?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #4.

4. Does the patient have a diagnosis of advanced or metastatic breast cancer and meet **ONE** of the following criteria?
   - The requested medication will be used as a single agent, if an anthracycline- or taxane-containing chemotherapy is not indicated
   - The requested medication will be used in combination with docetaxel after disease progression on prior anthracycline-containing chemotherapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #5.

5. Does the patient have a diagnosis of unresectable or metastatic gastric, esophageal, or gastroesophageal junction cancer and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The requested medication will be used as part of a combination chemotherapy regimen

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #6.

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CAPECITABINE

GUIDELINES FOR USE (CONTINUED)

6. Does the patient have a diagnosis of HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has not received prior treatment for metastatic disease
   - The requested medication will be used as part of a combination regimen

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #7.

7. Does the patient have a diagnosis of pancreatic adenocarcinoma and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The requested medication will be used as adjuvant treatment
   - The requested medication will be used as part of a combination chemotherapy regimen

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CAPECITABINE (Xeloda)** requires the following rule(s) to be met for approval:
   A. You have ONE of the following diagnoses:
      1. Stage III colon cancer (colon cancer that has spread to lymph nodes)
      2. Locally advanced rectal cancer (cancer that has spread from where it started to nearby tissue or lymph nodes)
      3. Unresectable (unable to remove by surgery) or metastatic colorectal cancer (a type of digestive cancer that has spread to other parts of the body)
      4. Metastatic breast cancer (breast cancer that has spread to other parts of the body)
      5. Unresectable or metastatic gastric, esophageal, or gastroesophageal junction cancer (a type of digestive system cancer that has spread to other parts of the body)
      6. HER2 (a type of protein)-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma (a type of digestive system cancer that has spread to other parts of the body)
      7. Pancreatic adenocarcinoma (a type of cancer of the pancreas)
   B. **If you have Stage III colon cancer, approval also requires:**
      1. The requested medication will be used as adjuvant (add-on) treatment

   (Denial text continued on next page)

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CAPECITABINE

GUIDELINES FOR USE (CONTINUED)

C. **If you have locally advanced rectal cancer, approval also requires:**
   1. You are 18 years of age or older
   2. The requested medication will be used as perioperative (the time period before and after surgery) treatment
   3. The requested medication will be used as part of chemoradiotherapy (a type of cancer treatment)

D. **If you have advanced or metastatic breast cancer, approval also requires ONE of the following:**
   1. The requested medication will be used as a single agent (used alone), if an anthracycline (such as doxorubicin, daunorubicin)- or taxane (such as paclitaxel, docetaxel)-containing chemotherapy is not indicated
   2. The requested medication will be used in combination with docetaxel after disease progression (worsens) on prior anthracycline (such as doxorubicin, daunorubicin)-containing chemotherapy

E. **If you have unresectable or metastatic gastric, esophageal, or gastroesophageal junction cancer, approval also requires:**
   1. You are 18 years of age or older
   2. The requested medication will be used as part of a combination chemotherapy (drugs used to treat cancer) regimen

F. **If you have HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma, approval also requires:**
   1. You are 18 years of age or older
   2. You have not received prior treatment for metastatic disease
   3. The requested medication will be used as part of a combination regimen (such as with cisplatin, trastuzumab)

G. **If you have pancreatic adenocarcinoma, approval also requires:**
   1. You are 18 years of age or older
   2. The requested medication will be used as adjuvant (add-on) treatment
   3. The requested medication will be used as part of a combination chemotherapy regimen (such as with gemcitabine)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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CAPECITABINE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xeloda.

REFERENCES

- Xeloda [Prescribing Information]. South San Francisco, CA: Genentech Inc., December 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/23/23
Created: 02/13
Client Approval: 01/23
P&T Approval: 01/23