

Submitted by:

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NCCN Guidelines Panel: Colon/Rectal/Anal Cancers Guideline Panel

On behalf of Genentech, I respectfully request the NCCN Colon/Rectal/Anal Cancers Guideline Panel to review the enclosed data on the use of Xeloda[®] (capecitabine) in combination with preoperative radiation therapy in patients with rectal cancer.

Specific Changes: For your consideration, data have been recently presented on Xeloda[®] (capecitabine) in combination with preoperative radiation therapy in patients with resectable adenocarcinoma of the rectum.¹

FDA Clearance: Xeloda in combination radiation therapy is not FDA-approved for rectal cancer. Xeloda is FDA-approved 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.² Xeloda is indicated as first-line treatment of patients with metastatic colorectal carcinoma when treatment with fluoropyrimidine therapy alone is preferred. Please refer to the enclosed prescribing information for the full FDA-approved indications and safety information.

Rationale: The National Surgical Adjuvant Breast and Bowel Project (NSABP) R-04 is a Phase III, randomized study evaluating four chemotherapy regimens administered concomitantly with preoperative radiation therapy. The study compares Xeloda with or without oxaliplatin against 5-fluorouracil with or without oxaliplatin. The endpoints are complete pathologic (pCR), sphincter-saving surgery (SSS), surgical downstaging (SD), and safety. There were no significant differences in pCR, SSS, and SD between the Xeloda and 5-fluorouracil arms or between the regimens with and without oxaliplatin. Patients who received oxaliplatin had significantly more Grade 3 or 4 diarrhea.

Due to copyright reasons, we are unable to provide a reprint of the abstract at this time. Please go to www.asco.org to view the abstract.

The following enclosures are included for your review (copyright-paid where applicable):

- Xeloda Prescribing Information

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Cited References

1. Roh MS, Yothers GA, O'Connell MJ, et al. The impact of capecitabine and oxaliplatin in the preoperative multimodality treatment in patients with carcinoma of the rectum: NSABP R-04. J Clin Oncol 29: 2011. ASCO Abstract #3503.
2. Xeloda Prescribing Information