On behalf of Genentech, I respectfully request the NCCN Esophageal/Gastric Cancers Panel to review the enclosed data on the use of Xeloda® (capecitabine) in gastric cancer.

Specific Changes: For your consideration, data have been presented on adjuvant Xeloda® (capecitabine) and oxaliplatin for gastric cancer.¹²

FDA Clearance: Xeloda in combination with oxaliplatin is not FDA-approved for gastric 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.³ 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: A Phase III, randomized, open-label, multicenter, international (South Korea, China, and Taiwan) study compared adjuvant Xeloda in combination with oxaliplatin (XELOX) to observation in previously untreated patients with Stage II, IIIa, or IIIb gastric cancer who underwent curative D2 gastrectomy.¹² The primary endpoint was 3-year disease-free survival (DFS). In a pre-planned interim analysis, the 3-year DFS was significantly higher in the XELOX arm compared with the observation arm, respectively. The most common adverse events (>50%) in the XELOX arm were nausea, neutropenia, and peripheral neuropathy.

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


- Xeloda Prescribing Information
Cited References


3. Xeloda Prescribing Information