On behalf of Genentech, I respectfully request the NCCN Non-small Cell Lung Cancer Guideline Panel to consider the following changes for Tarceva® (erlotinib) in patients with advanced non-small cell lung cancer (NSCLC).

Specific Changes:
1. Consider clarifying and changing the statement “Erlotinib is indicated as a first-line therapy in patients with EGFR mutation.” to reflect that Tarceva is not FDA-approved in this setting, though NCCN does list it as a Category 1 option.
2. On pages NSCL-14, -15, and -16, consider adding clarification in a footnote that Tarceva is indicated for maintenance, second-line, and third-line settings for locally advanced or metastatic NSCLC regardless of EGFR mutation status.

FDA Clearance: Tarceva monotherapy is indicated for the treatment of patients with locally advanced or metastatic NSCLC after failure of at least 1 prior chemotherapy regimen and the maintenance treatment of patients with locally advanced or metastatic NSCLC whose disease has not progressed after 4 cycles of platinum-based first-line chemotherapy. Results from two, multicenter, placebo-controlled, randomized, Phase III trials conducted in first-line patients with locally advanced or metastatic NSCLC showed no clinical benefit with the concurrent administration of Tarceva with platinum-based chemotherapy [carboplatin and paclitaxel or gemcitabine and cisplatin] and its use is not recommended in that setting. Please refer to the enclosed prescribing information for the full FDA-approved indications and safety information.

Rationale:
1. Tarceva is currently not FDA-approved, i.e. “indicated”, in the United States for the first-line setting in patients with advanced NSCLC who are EGFR mutation-positive, although, the NCCN guidelines lists Tarceva as a Category 1 recommendation.
2. Per the FDA-approved indication and pivotal trials, Tarceva may be used as an option for patients with locally advanced or metastatic NSCLC in the following settings regardless of EGFR mutation status: maintenance, second-line, and third-line settings.

Cited References

1. Tarceva Prescribing Information

Cc: Iris Tam, PharmD, Director, Managed Care Medical Communications