On behalf of Genentech, Inc., I respectfully request the NCCN NSCLC Guideline Panel to review the enclosed recent key publications for:

- **Avastin® (bevacizumab). Tarceva® (erlotinib): NSCLC**


**Specific Changes:**
There are no specific changes being requested. We are providing the full manuscript for recently submitted data evaluating Avastin plus Tarceva in NSCLC for your review and consideration.

**FDA Clearance:** Avastin is FDA-approved for first-line treatment of non-squamous NSCLC in combination with carboplatin and paclitaxel in patients with unresectable, locally advanced, recurrent or metastatic disease. Tarceva is a kinase inhibitor indicated for first-line treatment of patients with NSCLC whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test; maintenance treatment of patients with locally advanced or metastatic NSCLC whose disease has not progressed after four cycles of platinum-based first-line chemotherapy; and treatment of locally advanced or metastatic NSCLC after failure of at least one prior chemotherapy regimen. Tarceva is not recommended for use in combination with platinum-based chemotherapy. Safety and efficacy of Tarceva have not been evaluated as first-line treatment in patients with metastatic NSCLC whose tumors have EGFR mutations other than exon 19 deletions or exon 21 (L858R) substitution.

Please refer to the enclosed prescribing information for the full FDA-approved indications and safety information.

**Rationale:**
Results demonstrating a significant improvement in the primary outcome measure of progression-free survival (PFS), in addition to results for tumor response related secondary outcome measures and biomarker sub-analysis have been previously submitted for this phase II trial combining Avastin and Tarceva in non-squamous NSCLC patients. Data for the secondary outcome measure of overall survival is not yet mature. The recently published full manuscript for this study is now being submitted for your review. Additional data on the use of Avastin in combination with Tarceva in NSCLC with subset analyses on EGFR+ patients have been reported.1-7 There are also two ongoing trials with Avastin in combination with Tarceva in EGFR positive NSCLC patients specifically.8-9
Supplemental References


