On behalf of Boehringer-Ingelheim Pharmaceuticals, Inc., I respectfully request the NCCN Non-Small Cell Lung Cancer Guidelines Panel review the enclosed data for inclusion of afatinib (Gilotrif®) in combination with cetuximab (Erbitux®) as subsequent therapy for treatment of patients with sensitizing EGFR mutations who develop acquired resistance to EGFR tyrosine kinase inhibitor (TKI) treatment (NSCL-17).

Specific Changes:

Add afatinib (Gilotrif®) in combination with cetuximab (Erbitux®) for:
   a. Subsequent therapy for patients with sensitizing EGFR mutations who develop acquired resistance to EGFR TKI treatment (NSCL-17)

Rationale:

Currently, there are no EGFR targeted therapies approved for the treatment of patients who develop acquired resistance following NCCN (Category 1) recommended treatment with an EGFR TKI. In the attached publication, the authors concluded that treatment with afatinib in combination with cetuximab “conferred robust and durable clinical responses irrespective of T790M status, combined with a manageable safety profile” in this population of patients.

FDA Clearance:

On July 12, 2013, the FDA cleared the use of afatinib for the first line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have EGFR exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA approved test. This approval includes the following limitation of use: Safety and efficacy of Gilotrif™ have not been established in patients whose tumors have other EGFR mutations.
The following article is submitted in support of this proposed change. We would like to acknowledge the contributions of NCCN panel members who are also co-authors or co-contributors of this publication.


Sincerely,

[Signature]

Elizabeth Terlizzi, RN, BSN, MPH