Submitted by:
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On behalf of Boehringer-Ingelheim Pharmaceuticals, Inc., I respectfully request the
NCCN Non-Small Cell Lung Cancer Guidelines Panel to review the enclosed data for inclusion
of afatinib (Gilotrif™) for treatment of advanced squamous cell carcinoma of the lung following
progression on or after platinum based chemotherapy.

Specific Changes:
Add afatinib (Gilotrif™) for subsequent therapy for the treatment of patients with advanced
squamous cell carcinoma of the lung (SCC) following progression on or after platinum based
chemotherapy.

Rationale:
Currently, there is a major unmet need for effective treatments in patients with squamous cell
carcinoma (SCC) of the lung following failure of platinum-based chemotherapy. One of the
treatments approved by the FDA and listed in the NCCN Guidelines is erlotinib. Recently, a
randomized comparison of erlotinib and afatinib was carried out in patients with advanced
squamous cell carcinoma of the lung following platinum based chemotherapy. The results of this
study showed that treatment with afatinib improved both progression free survival and overall
survival as compared to treatment with erlotinib. Afatinib was also associated with improvements
in disease control rate, patient related outcomes, and disease-related symptoms versus erlotinib.
The pattern of adverse events was similar between treatments and consistent with their already
established safety profile.

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 (including supplemental material) and editorial are submitted in support of
this proposed change.

second-line treatment of patients with advanced squamous cell carcinoma of the lung (LUX-Lung
8): an open-label randomised controlled phase 3 trial. Lancet Oncol 2015; published online July

Hirsch FR, Herbst RS, Gandara DR. EGFR tyrosine kinase inhibitors in squamous cell lung
cancer. Lancet Oncol 2015; published online July 6. http://dx.doi.org/10.1016/S1470-
2045(15)00126-6

Sincerely,

Elizabeth Terlizzi