



## Positive Quality Intervention: EGFR Inhibitors

**Description of PQI:** For patients with Non-Small Cell Lung Cancer (NSCLC) that have a del 19 EGFR mutation appropriate for first-line treatment with an epidermal growth factor receptor (EGFR) Inhibitor, Afatinib (Gilotrif) has a clear overall survival (OS) benefit compared to chemotherapy. If another EGFR inhibitor is being prescribed for a patient with a del 19 EGFR mutation, the pharmacist will contact the Physician to determine why the current therapy was chosen.

**Background:** In the LUX-Lung 3 trial, in del 19 EGFR mutation patients, Afatinib is the first EGFR inhibitor to demonstrate an improvement in overall survival (OS) when compared to Cisplatin/Pemetrexed. Median overall survival was 33.3 months in the Afatinib arm compared to 21.1 months in the chemotherapy arm. Subsequently, In the LUX-Lung 6 trial, in del 19 EGFR mutation patients, Afatinib likewise demonstrated an improvement in overall survival (OS) when compared to Cisplatin/Gemcitabine. Median overall survival was 31.4 months in the Afatinib arm compared to 18.4 months in the chemotherapy arm.

**PQI process:** Using the practice's EMR

- Identify newly diagnosed metastatic NSCLC patients Stage IIIB/IV adenocarcinoma
- Confirm that EGFR mutational testing was done
  - If not done, document reason why EGFR mutational testing was not done
  - If results are pending, what is the plan?
    - Wait and start EGFR inhibitor if positive
    - Wait and start chemotherapy if negative
    - Begin chemotherapy regardless of result
- If EGFR mutational testing was done, document whether it was positive or negative
  - If negative, no further information is required
  - Documentation of choice of chemotherapy
- If EGFR mutation is positive, document the type of mutation: del 19 (exon19), L858R (exon21) or other
- Document 1 of the following 4 treatment choices:
  - Afatinib (Gilotrif)
  - Erlotinib (Tarceva)
  - Gefitinib (Iressa)
  - Chemotherapy
- **If patient has del 19 EGFR mutation and prescribed Erlotinib or Gefitinib, discuss with Physician the overall survival benefit of Afatinib in this patient population. Document the outcome of discussion.**
- Document the starting dose and schedule of the first three choices
  - Document reason why any other dose/schedule is given than what is indicated
  - Document if a starter kit was given to patient.
- If chemotherapy was chosen, document the reason why it was selected

**Important notice:** National Community Oncology Dispensing Association, Inc. (NCODA), has developed this Positive Quality Intervention platform. This platform represents a brief summary of medication uses and therapy options derived from information provided by the drug manufacturer and other resources. This platform is intended as an educational aid and does not provide individual medical advice and does not substitute for the advice of a qualified healthcare professional. This platform does not cover all existing information related to the possible uses, directions, doses, precautions, warning, interactions, adverse effects, or risks associated with the medication discussed in the platform and is not intended as a substitute for the advice of a qualified healthcare professional. The materials contained in this platform are for informational purposes only and do not constitute or imply endorsement, recommendation, or favoring of this medication by NCODA, which assumes no liability for and does not ensure the accuracy of the information presented. NCODA does not make any representations with respect to the medications whatsoever, and any and all decisions, with respect to such medications, are at the sole risk of the individual consuming the medication. All decisions related to taking this medication should be made with the guidance and under the direction of a qualified healthcare professional.



**Dosing:** Afatinib 40mg once daily (One hour before or 2 hours after a meal)

**Adverse Events:** Most common adverse events were Diarrhea 96% (Grade 3-15%), Rash/Dermatitis Acneiform 70% (Grade 3-16%), Stomatitis 71% (Grade 3-9%), Paronychia 58% (Grade 3-11%), Dry Skin 31%, Decreased Appetite 29% (Grade 3-4%)

**Dosing Modifications:** Tolerability-guided dose modification does not affect the efficacy of Afatinib and is an effective measure to reduce treatment related adverse events and potential drug discontinuation

- Dose modifications have occurred in as many as 53% of patients in previous trials. Majority (82-86%) occurring within the first 6 months of treatment
- Reducing the dose has been found to not affect PFS
- Adverse events were significantly less in patients following dose reductions
- Diarrhea – If a patient experiences Grade 2 or higher diarrhea for 2 or more consecutive days despite anti-diarrheal therapy, interrupt therapy until diarrhea resolves to grade 1 or less and restart on 10mg less than previous dose
  - Patients should be sent home with anti-diarrheals (Imodium) and educated that diarrhea may occur in the first two weeks.
  - Grade 1 Diarrhea – Increase of <4 stools per day over baseline
  - Grade 2 Diarrhea- Increase of 4 to 6 stools per day over baseline

**Dose modification references:** Lancet Oncology, Yang et. al. Jan 2015; Annals of Oncology 27: 2103–2110, 2016

**Labs:** Periodic renal and hepatic function

**Patient Centered Activities:**

- Provide Oncology Chemotherapy Education (OCE) sheet
- Supply Anti Diarrheals
- Supply Moisturizing cream
- Supply Sun Screen

**Additional Indication:** For the treatment of metastatic squamous NSCLC, progressing after platinum-based chemotherapy

- Platinum-resistant metastatic squamous NSCLC patients treated with Afatinib experienced significant improvements in PFS compared with Erlotinib (2.4 vs. 1.9 months-LUX Lung 8).

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