National Community Oncology Dispensing Association, Inc.
PASSION FOR PATIENTS

Written by: Danny Olszta, PharmD, BCOP
Jolliet Oncology Hematology Associates

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 <u>Afatinib</u> 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

National Community Oncology Dispensing Association, Inc.
PASSION FOR PATIENTS

Written by: Danny Olszta, PharmD, BCOP
Jolliet Oncology Hematology Associates

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).