



ABSTRAK

Non-small cell lung cancer merupakan jenis kanker paru yang paling banyak terjadi. Sekitar 80% merupakan pasien dengan stadium lanjut dan sampai 50% mengalami mutasi *epidermal growth factor receptor*. EGFR-Tyrosin Kinase Inhibitors (TKIs) merupakan terapi lini pertama yang digunakan seperti afatinib dan gefitinib. Beberapa penelitian menunjukkan afatinib memiliki efektivitas (*Progression Free Survival/PFS* dan *Overall Survival/OS*) lebih baik dibandingkan dengan gefitinib namun memiliki harga yang lebih tinggi dibandingkan gefitinib, sehingga perlu dilakukannya *Health Technology Assessment* untuk meningkatkan kendali mutu dan kendali biaya pada pelayanan kesehatan dalam era Jaminan Kesehatan Nasional (JKN) agar pemilihan serta penggunaan obat yang lebih efektif dan efisien. Penelitian ini bertujuan untuk melakukan analisis farmakoekonomi afatinib dan gefitinib pada pasien NSCLC dengan mutasi EGFR.

Analisis unit biaya dilakukan dengan menggunakan pendekatan observasional secara retrospektif dan rancangan penelitian *cross sectional* dengan perspektif *health provider* dan *societal*. Penelitian *cost effectiveness analysis* dilakukan menggunakan desain kohort dengan pendekatan studi farmakoekonomi berbasis studi observasional, dengan luaran efektivitas berupa PFS dan OS yang dilihat dari catatan rekam medik pasien. Penelitian *cost utility analysis* dilakukan menggunakan pendekatan dengan teknik *modelling (markov model)* dengan perspektif *health provider* dan *societal* dengan *time horizon* seumur hidup (*life time*) serta lama siklus 1 bulan dan *discount rate* 3% dimana untuk probabilitas transisi diperoleh dari studi literatur sedangkan biaya dan utilitas dari studi observasional.

Rata-rata biaya pada pasien NSCLC mutasi EGFR yang menggunakan afatinib sebesar Rp. 120.881.289,- dan gefitinib sebesar Rp. 90.750.186,-. Skore utilitas pada pasien NSCLC mutasi EGFR pada kondisi *profession free* yaitu 0,824 dan kondisi *progressive disease* 0,537. Nilai ICER selisih antara afatinib dengan gefitinib berdasarkan *outcome* klinik PFS yaitu 106 Rp.106.345.069,4/tahun dimana nilai ICER lebih kecil dari 2 kali GDP yaitu sekitar 1,8 kali dari nilai GDP. Nilai ICER berdasarkan QALYs pada perspektif *societal* yaitu Rp.102.609.620 per QALYs, sedangkan perspektif *provider* dihasilkan nilai ICER Rp. 101.172.112/QALYs. Dari kedua perspektif tersebut nilai ICER yang diperoleh lebih kecil dibandingkan WTP/CE-threshold yaitu Rp. 177.300.000,-. Penggunaan afatinib pada pasien NSCLC dengan mutasi EGFR terbukti meningkatkan PFS (*outcome* klinik) dan QALYs dan *cost effective*.

Kata kunci: Farmakoekonomi, afatinib, gefitinib, *Non-small cell lung cancer*



ABSTRACT

Non-small cell lung cancer is the most common type of lung cancer. It is about 80% are patients with an advanced stage and up to 50% have mutations in the epidermal growth factor receptor. EGFR-Tyrosin Kinase Inhibitors (TKIs) are the first-line therapies used, such as afatinib and gefitinib. There are several studies have been shown that afatinib is better effectiveness (PFS and OS) than gefitinib unfortunately it has higher price than gefitinib, so it is necessary to do a Health Technology Assessment to improve the quality control and also cost control in the health services in the era of the National Health Insurance (JKN) so that the selection and use of these drugs are more effective and efficient. The aim of this study was to perform a pharmacoeconomic analysis of afatinib and gefitinib in NSCLC patients with EGFR mutations.

The unit cost analysis used a retrospective observational approach and used a cross-sectional study design using a health provider and societal perspective. In the cost-effectiveness analysis study, using a cohort design with a pharmacoeconomic study approach based on an observational study, with outcome effectiveness in the form of progression free survival and overall survival as seen from the patient's medical record. In this research, cost utility analysis are used an approach with combination of modeling techniques (Markov model) with a health provider and also societal perspective. It is observed with a lifetime time horizon and a cycle length of 1 month and a discount rate of 3% where the transition probability is obtained from the literature studies, while the costs and utilities are observed from the observational studies. The cost average for EGFR mutated NSCLC patients using afatinib and gefitinib of Rp. 120,881,289, - and Rp. 90,750,186, - respectively. The utility score in NSCLC patients with EGFR mutations in the progression free condition of 0.824 and the progressive disease condition of 0.537. The ICER value of the difference between afatinib and gefitinib based on the PFS clinical outcome was 106 Rp. 106,345,069.4 / year where the ICER value was less than 2 times from the GDP value, it was around 1.8 times the GDP value. The ICER value based on QALYs from a societal perspective is about Rp. 102,609,620 per QALYs, while the provider perspective results in an ICER value of Rp. 101,172,112/QALYs. From these two perspectives, the ICER value obtained is smaller than the WTP / CE-threshold, namely Rp. 177.300.000, -

The use of afatinib in NSCLC patients with EGFR mutations has been shown the increasing of the PFS (clinical outcome) and QALYs and the cost effective of QALYs.

Key words: Pharmacoeconomics, afatinib, gefitinib, Non-small cell lung cancer.