Budget Impact Analysis of Pemetrexed Introduction: Case Study from a Teaching Hospital Perspective, Thailand

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Objective: *Thailand does not currently require Budget Impact Analysis (BIA) assessment. The present study aimed to estimate the annual drug cost and the incremental impact on the hospital pharmaceutical budget of the introduction of pemetrexed to a Thai teaching hospital.*
Material and Method: *The budget impact model was conducted in accordance with the Guidelines for preparing submissions to the Pharmaceutical Benefits Advisory Committee (PBAC). The model variables consisted of number of patients, growth rate of lung cancer, uptake rate of pemetrexed over time, unit prices of drugs, and the length and cost of treatment. Sensitivity analysis was performed to determine changes in budgetary impact due to variation of parameters or assumptions in the model.*
Results: *The introduction of pemetrexed was estimated to cause considerable costs for the teaching hospital. In the base-case analysis, the incremental costs were estimated at 8,553,984 Baht in the first year increasing to 12,118,144 Baht, 17,820,800 Baht and 17,820,800 Baht in the following years. The 4-year net budgetary impact was 20,154,480 Baht or approximately 127,560 Baht per patient. Sensitivity analyses found that number of treatment cycles and proportion of patients assumed to be treated with pemetrexed were the two most important influencing factors in the model.*
Conclusion: *New costly innovative interventions should be evaluated using the BIA model to determine whether they are affordable. The Thai government should consider requiring the BIA study as one of the requirements for drug submission to assist in the determination of listing and subsidizing decision for medicines.*

Keywords: *Budget impact analysis, Pemetrexed, Teaching hospital, Pharmaceutical subsidization*

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Currently, cancer is a leading cause of death globally. In 2004, approximately 7.4 million deaths worldwide were caused by cancer and it is predicted to increase with an estimated 12 million deaths in 2030. Cancer is the second major cause of death following cardiovascular disease in most developed countries. Lung cancer accounted for 1.3 million deaths annually and is the most common type of cancer in men. Other major types of cancer contributing to overall cancer mortality each year are stomach, colorectal, liver and breast[1,2].

In Thailand, lung cancer accounted for 48% of all cancer types[3]. Approximately 80% of all cases of lung cancer are non-small cell lung cancer (NSCLC)[4,5]. Patients with untreated metastatic NSCLC have median survival of only four to five months[6]. Platinum-based chemotherapy has been found to improve survival rates of these patients[7].

Pemetrexed (Alimta, Eli Lilly and Company) is an antifolate containing the pyrrolopyrimidine-based nucleus that disrupts folate-dependent metabolic processes necessary for cell 21 replication[8]. It has been approved by the US Food and Drug Administration as an anticancer agent for chemotherapy-naive patients with malignant pleural mesothelioma in combination with cisplatin. It has also obtained approval as a single agent for second-line therapy in the treatment of patients with locally advanced or metastatic (Stage III or IV) NSCLC after prior chemotherapy[8]. Recently, pemetrexed has been approved for initial treatment of locally advanced or metastatic nonsquamous NSCLC in combination with cisplatin[9].

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Although studies showed that pemetrexed has proven cost-effective, there is still a need to further evaluate whether the hospital can afford its cost if the drug is included into the hospital formulary. Budget impact analysis (BIA) is a powerful instrument currently been used in many countries, for estimating the impact of new drugs or health interventions on government budgets[10-15]. In some EU countries, *e.g.* the United Kingdom (UK), Germany, France, Italy, Sweden, Spain, and the Netherlands, BIA is used as a criterion to determine pharmaceutical reimbursement[14]. In Canada and many Organization for Economic Co-operation and Development (OECD) countries, the economic evaluations and budget impact studies for new drugs from pharmaceutical manufacturers are required to be submitted by the drug programs[15]. Drug plans in Canada require manufacturers to submit BIAs as part of their submission package for listing purposes. Furthermore, some developed countries such as Australia (by the Pharmaceutical Benefits Advisory Committee; PBAC), the UK (by the National Institute for Clinical Excellence; NICE) and the Netherlands (by the Sickness Funds Council) have requested pharmaceutical companies to submit the BIA study to the health authorities in parallel with the economic evaluation to assist in the reimbursement decision or formulary listing[16]. In Thailand, there are researches concerning BIA conducted from several perspectives such as the use of BIA to estimate the financial impact on the extension of renal replacement therapy into the Universal Coverage Scheme[13] and the BIA model evaluating direct medical costs for severe thalassemic patients[17]. However, differently from some developed countries mentioned above, it is not required by the Food and Drug Administration that the BIA study has to be submitted as part of the drug submission.

In this retrospective pre-post research, a budget impact model was developed to estimate the annual drug cost and the incremental impact on the pharmaceutical budget of the introduction of a high price innovator drug, pemetrexed into a teaching hospital to predict the increase in hospital's drug expenditure and forecast the budget impact for the four years after its introduction. The present study was conducted from the hospital budget perspective.

Material and Method

This method was developed in accordance with the procedure advised in the Section E of the Guidelines for preparing submissions to the Australian Government Pharmaceutical Benefits Advisory Committee (Version 4.3**)** currently been used for drug submission in Australia[18].

Study design, perspective and time horizon

This retrospective pre-post research aimed to estimate the annual drug cost and incremental impact on the pharmaceutical budget of the introduction of a high-price innovator drug, pemetrexed, into a teaching hospital formulary. It was conducted from the hospital budget perspective. In this teaching hospital, pemetrexed is prescribed as one of the anticancer drugs for cancer patients. Only drug costs charged to the patients were included in the present study. Baseline data was set at fiscal year 2005 as pemetrexed was first introduced in early fiscal year 2006. Forecasted impact on the drug budget of the hospital was conducted for the fiscal years 2006 to 2009. Budget impact results were not discounted nor inflated. Costs are displayed in Thai Baht (Baht).

Population

The present study population was patients in the hospital who were diagnosed as lung cancer patients. Both inpatients and outpatients were included.

Scenarios to be compared

The reference scenario was NSCLC patients treated with docetaxel (current practice). The comparative scenario was NSCLC patients assumed to be treated with pemetrexed**.**

Data sources and data collection

The hospital admissions database was used as the primary data source. The database contained information on the drug utilization profile for cancer patients with diagnosis codes indicating neoplasms anywhere in the body (International Classification of Diseases; ICD-10 code C00-D48)[19] that were enrolled in the hospital between the fiscal years 2005 and 2009 (October 1, 2004 to September 30, 2009). Parameters included in the database were patients' ID number, hospital admission number, name of drugs used, quantity and dose of drugs used, unit price of drugs, date of supply, doctors' ID number, bill amount and insurance status. The hospital cancer registry was also used to identify cancer patients.

Data analysis

Budget Impact Analysis performed in the present study for the fiscal years 2006 to 2009 was

conducted in accordance with Section E of the Guidelines for preparing submissions to the Pharmaceutical Benefits Advisory Committee (Version 4.3)[18].

The budget impact model

The model took into account the number of patients, the incidence rate of lung cancer patients, the uptake rate of pemetrexed over time, unit prices of drugs, and the length and cost of treatment. Assumptions and estimates for the parameters in the model were derived from the hospital database and published sources of information.

The model consists of four steps. In the first step, estimation of numbers of patients with lung cancer and NSCLC were made. The hospital database was used to identify the population of treated lung cancer patients (ICD-10 code C34) in the hospital in 2005. Since the growth rate of the lung cancer incidence for Thailand was not available, the Australian cancer incidence data between fiscal years 2000 and 2005 was used as an information source to estimate the incidence rate of lung cancer patients[20]. Details of the incidence rate are shown in Table 1.

To estimate the number of patients with NSCLC, who were the target population for pemetrexed use, a peer-reviewed published study by Rossi, et al[5] was used which estimated that NSCLC accounted for more than 80% of cancer patients. No other published literature reporting incidence rates was found.

Estimation of the proportion of patients eligible for pemetrexed use was performed in step 2. Docetaxel was considered the comparator for pemetrexed as it was also the comparator in the randomized controlled trial[4]. The proportion of patients treated with docetaxel in the fiscal year 2005 was used to estimate the numbers of patients who were likely to be treated with or switched to pemetrexed. The uptake rate of pemetrexed use was assumed and set to be 50, 70, 100 and 100% over the four years. This assumption was varied in the sensitivity analysis. Docetaxel had been in use since 1999 therefore, it was assumed that docetaxel use in 2005 reflected stable use.

In the third step, total drug costs for pemetrexed and docetaxel were estimated. Data were extracted from the hospital data set. Hospital drug costs for pemetrexed and docetaxel are shown in Table 2.

The recommended dose of pemetrexed is 500 mg/m^2 administered intravenously over one hour every three weeks[8]. The number of cycles to be treated is recommended at four cycles with a maximum of six cycles[21,22]. Assuming that an adult would have the body surface area of 1.7 m^2[23], the assumed dose for one patient would be 850 mg of pemetrexed per cycle. Hence, an adult patient would have to use two vials for one treatment cycle equivalent to eight vials for four treatment cycles.

The cost offsets were estimated based on reduced use of docetaxel. The recommended dose of docetaxel is 75 mg/m^2 administered as an intravenous infusion over 10 minutes on day 1 of each 21-day cycle. The number of cycles to be treated is recommended at four cycles with a maximum of six cycles[21,22]. Assuming that an adult would have the body surface area of 1.7 m^2[23], the assumed dose for one patient would be 127.5 mg of docetaxel per cycle. Hence, an

Table 1. Incidence rate of lung cancer patients in Australia during 2000-2005

Year	2000	2001	2002	2003	2004	2005
Number of patients	8,224	8,373	8,549	8,434	9,175	9,167
% increase	1.81	2.10	-1.35	8.79	-0.09	N/A
Average			2.25%			

Table 2. Drug costs

Generic name	Trade name	Recommended dose	Price per unit (Baht)
Pemetrexed 500 mg/20 ml intravenous injection	Alimta	500 mg/m^2	44,552
Docetaxel 80 mg/2 ml intravenous injection	Taxotere	75 mg/m^2	31,252
Docetaxel 20 mg/2 ml intravenous injection	Taxotere	75 mg/m^2	8,654

adult patient would have to use one vial of 80 mg/2 ml and three vials of 20 mg/0.5 ml for one treatment cycle equivalent to 16 vials for four treatment cycles.

The financial implication for the hospital was estimated in the final step. BIA was conducted by calculating the total drug costs and determining the incremental cost of pemetrexed introduction for the fiscal years 2006 to 2009. The total drug cost was defined by multiplying the number of patients who used pemetrexed each year identified in step 2 with the total drug cost for pemetrexed examined in step 3. Cost offsets were determined by multiplying the number of patients who used docetaxel each year in step 2 with the total drug cost for docetaxel examined in step 3. The incremental cost of pemetrexed introduction was identified by subtracting the total cost docetaxel from that of pemetrexed.

Sensitivity analyses

Sensitivity analysis was performed to determine the changes in budgetary impact from the variation or uncertainty of parameters and assumptions in the budget impact model. Parameters varied included number of patients, uptake rate, growth rate of the disease incidence, and length of treatment cycles. Worst-case sensitivity analysis identified the net cost to the hospital when numbers of patients, uptake rate, and length of treatment cycles were increased to the upper reasonable estimates. Net cost changes when decreasing the numbers of patients, uptake rate, and length of treatment cycles to the lower possible estimates were determined in the best-case sensitivity analysis.

Results

Base-case results

The estimated number of patients treated started at 588 in year one rising to 629 in year four. The overall cost for pemetrexed in the first year after the introduction of pemetrexed, was estimated at 8,553,984 Baht or approximately 127,560 Baht per patient. In the following years, the estimated drug costs increased to 12,118,144 Baht, 17,820,800 Baht and 17,820,800 Baht, respectively. The overall cost offsets (reduced cost of docetaxel use) were estimated to be 5,492,544 Baht, 7,781,104 Baht, 11,442,800 Baht and 11,442,800 Baht, respectively (Table 3).

Assuming no patient cost sharing and no other differences in costs would be incurred as both drugs are intravenous injections and require the same amount of nursing and infusion costs, overall medication costs for NSCLC patients over time were estimated to increase by 3,061,440 Baht in the first year after listing to 6,378,000 Baht in the fourth year after listing as a result of the introduction of pemetrexed.

The model results showed that the introduction of pemetrexed in the hospital's formulary increased the budgetary impact by the total amount of 20,154,480 Baht during the forecasted 4-year time. The full model and assumption are summarized in Table 3.

Sensitivity analyses

Sensitivity analyses using the worst-case scenario when parameters were varied to include a 7% increase of lung cancer incidence rate, 100% of the uptake rate and six treatment cycles showed the highest budget impact of 41,712,120 Baht. In contrast, the smallest budget impact of 6,633,120 Baht was found in the best-case scenario when it was assumed there was a 2% increase of lung cancer incidence rate, 5% of NSCLC patients received docetaxel and there was a 50% uptake rate. In the most costly scenario, the financial impact for the hospital increased by approximately 107% compared to the base-case analysis. On the contrary, a reduction of around 67% of the total cost was found in the least costly scenario.

The present study also revealed that the difference between short and long therapy (Worst-case 1 and 2) was 13,904,040 Baht for the 4-year period or about 3,476,010 Baht per year. Concerning the uptake rate, it was found that an extra budget of 7,653,600 Baht for four years or approximately 1,913,400 Baht would have to be added into the total cost per year if all eligible patients used the new drug from the beginning. A summary of the net budget impact for the sensitivity analyses is displayed in Table 4 and Fig. 1.

Discussion

The present study found that the introduction of pemetrexed caused considerable costs for the teaching hospital of interest. The introduction of pemetrexed to the hospital formulary was estimated to result in increased expenditure of 20,154,480 Baht or 127,560 Baht per patient. Based on this figure, the introduction of pemetrexed into the hospital might be considered unaffordable since the affordable threshold for introducing a new intervention in Thailand has been set at 100,000 Baht[24]. Under this circumstance, pemetrexed might not be appropriate for every eligible patient. Possible options for solving this issue might be to establish higher criteria for selecting

Table 3. Annual estimates of numbers of patients treated, numbers of prescriptions dispensed and costs to the hospital in the base-case scenario

Data	Fiscal year					Source/assumptions
	2005 (baseline)	2006	2007	2008	2009	
Numbers of patients						
- Numbers of lung cancer patients	575*	588	601	615	629	*The hospital data set/assume 2.25% increase rate of lung cancer incidence
- Numbers of NSCLC patients		500	511	522	534	Assume 85% of lung cancer patients
- Numbers of patients assumed to be treated with pemetrexed		47	48	49	50	Assume 9.4% treated with pemetrexed (based on the hospital data set, 9.4% of them or 47 patients were treated with docetaxel in the fiscal year 2005)
- Numbers of patients likely to be treated with pemetrexed		24	34	50	50	Assume the uptake rate of 50%, 70%, 100% and 100%
- Numbers of packs dispensed per year		192	272	400	400	Assume 4 treatment cycles per patient, 8 vials in total
Costs to the hospital for the listing of pemetrexed (Baht)						
- Unit cost of pemetrexed			44,552 Baht/vial			Assume no patient co-payment and no other differences in costs
- Total cost of pemetrexed		8,553,984	12,118,144	17,820,800	17,820,800	
- Savings to the hospital through reduced use of docetaxel		5,492,544	7,781,104	11,442,800	11,442,800	
- Net costs to the hospital		3,061,440	4,337,040	6,378,000	6,378,000	
- Incremental cost for 4 years			20,154,480			

Table 4. Summary of net budget impact for the sensitivity analyses

Assumptions	Comparing scenario				
	Worst-case 1	Worst-case 2	Worst-case 3	Best-case 1	Best-case 2
Rate of increase of lung cancer incidence (% increase per year)	7	7	7	2	2
Proportion of NSCLC patients receiving docetaxel (%)	N/A	N/A	N/A	5	5
Rate of uptake (% each year)	100	100	N/A	N/A	50
Number of treatment cycle	N/A	6	6	N/A	N/A
Net budget impact (Baht)	27,808,080	41,712,120	34,058,520	10,587,480	6,633,120

N/A = unchanged from base-case scenario

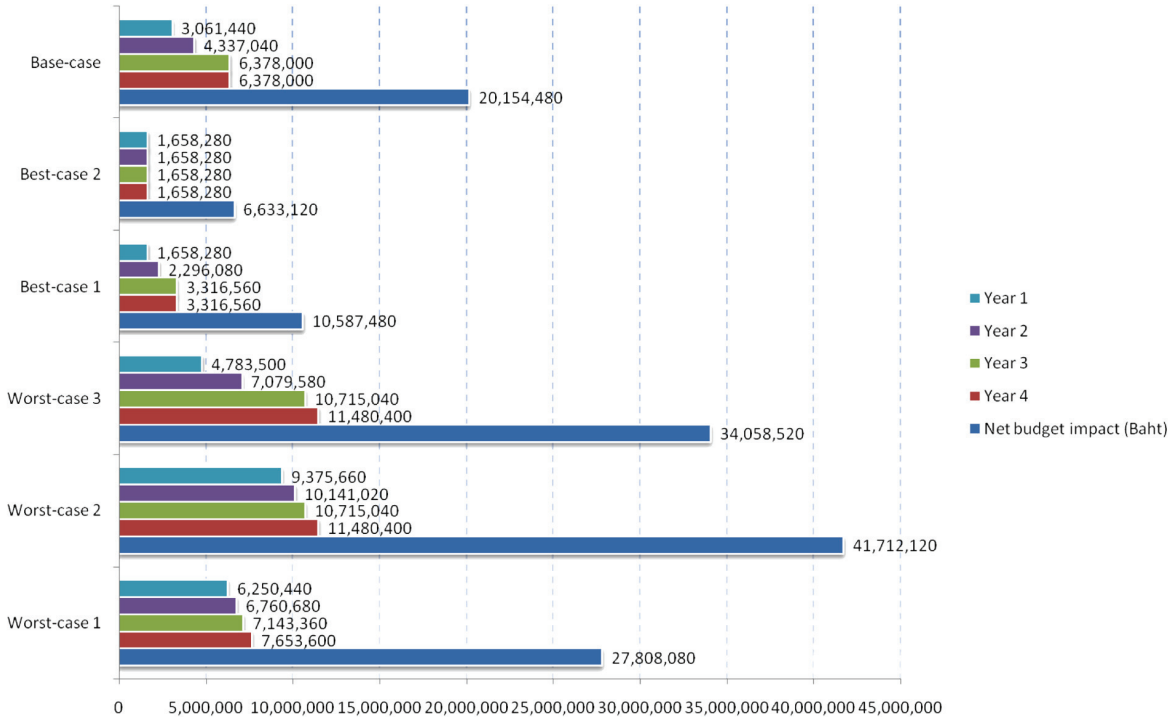

Fig. 1 Net budget impact of pemetrexed introduction in the sensitivity analyses and base case scenario

and prioritizing the patients with the most necessity and providing them with this treatment regimen.

Besides the affordability issue, consideration on the efficacy of drug should be addressed. Not only pemetrexed has been approved by the US Food and Drug Administration as a single agent for the treatment of patients with locally advanced or metastatic NSCLC after prior chemotherapy and for initial treatment of locally advanced or metastatic nonsquamous NSCLC in combination with cisplatin[9], recent update on chemotherapy by the American Society of Clinical Oncology published in 2009 also suggested using pemetrexed as one of four drugs for second-line therapy in stage IV NSCLC patients[25]. However, its clinical advantage has not proven statistically significant superiority over current treatment practice. Pemetrexed has been found to increase overall survival to 8.3 months compared to 7.9 months in docetaxel. It also has been found to improve objective response rate, increase progression free survival and increase time to progressive disease. However, these clinical benefits were statistically insignificant. Moreover, no significant difference in terms of changes in the Average Symptom Burden Index of the Patient Lung Cancer Symptom Scale was observed. Nevertheless, pemetrexed has proven significantly lower rates of neutropenia, neutropenic fever, infections and hospitalization due to neutropenic events[4]. Given the fact that the drugs used in late stages are not for curative purpose, the decision to select pemetrexed for the hospital should be considered extensively in order to make the most appropriate decision.

It should also be noted that the present study was undertaken in only one hospital, therefore, the introduction of pemetrexed across Thailand would add considerable expense. In addition, this is just one example of the expenditure for only one drug, other anticancer drugs costs would certainly have to be included into the total amount and could cause substantial impact to hospital budgets.

The sensitivity showed that that number of treatment cycles and proportion of patients assumed to be treated with pemetrexed were the two most important influencing factors in the model. The higher number of treatment cycles resulted in greater total budget while a smaller number of patients assumed to be eligible for the treatment of pemetrexed yielded less expense. Criteria for use would be a possible solution to maintain affordability. As a teaching hospital, variety of drug choices is usually available to the doctors.

Therefore, it would be useful to establish appropriate practice guidelines for the use of pemetrexed as proper treatment regimens not only reduce unnecessary costs but rational use of medicines can also benefit patients.

Some of the parameters in the BIA model are based on assumptions resulting in uncertainties in the present study. Thailand National statistical data concerning the actual rate of increase in the number of patients with lung cancer and NSCLC was not available. Therefore, the incidence growth rate had to be estimated from the Australian cancer data cube. It would be better to use the growth rate of the Thai people, as this would best reflect the real number of patients in the Thailand context. No off-label use was assumed in the present study. However, off-label use may be possible and greater drug expenditure may result.

As this BIA was performed from the hospital perspective, results from the present study would be beneficial to the management level of the hospital. However, it might not be applicable for hospitals in contexts other than teaching hospitals.

The BIA is useful for decision making for all levels of budget holding. New costly innovative interventions should be evaluated using the BIA model in order to determine whether they are affordable. Sensitivity analyses should be conducted.

Conclusion

Results from the present study revealed that the introduction of pemetrexed to the teaching hospital's formulary caused significant net budget impact. The number of treatment cycles and the proportion of eligible patients had considerable influence on the net financial impact. Future studies should be performed for other expensive medicines using national data or data from other hospitals. The Thai government should consider requiring the BIA as one of the requirements for drug submissions.

Potential conflicts of interest

None.

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การวิเคราะห์งบประมาณของยา pemetrexed: กรณีศึกษาจากมุมมองของโรงพยาบาลโรงเรียนแพทย์ในประเทศไทย

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วัตถุประสงค์: *ปัจจุบันประเทศไทยยังไม่มีการวิเคราะห์ผลกระทบด้านงบประมาณ การศึกษานี้มีวัตถุประสงค์เพื่อประมาณการณ์ต้นทุนด้านยาต่อปีและส่วนต่างของผลกระทบที่จะเกิดกับงบประมาณด้านยาของโรงพยาบาลโรงเรียนแพทย์เมื่อเริ่มมีการใช้ยา pemetrexed*

วัสดุและวิธีการ: *แบบจำลองผลกระทบด้านงบประมาณที่ศึกษานำมาจากแนวทางสำหรับการเตรียมเอกสารสำหรับการยื่นคำขอเกี่ยวกับยาเพื่อนำเสนอต่อ Pharmaceutical Benefits Advisory Committee (PBAC) ของประเทศออสเตรเลีย แบบจำลองนี้ประกอบด้วยตัวแปร ดังนี้ จำนวนผู้ป่วย อัตราการเพิ่มขึ้นของอุบัติการณ์การเกิดโรคมะเร็งปอด อัตราการใช้ยา pemetrexed ราคายา ระยะเวลาการใช้ยา และต้นทุนการรักษา การศึกษานี้ได้ทำการวิเคราะห์ความไวเพื่อศึกษาผลกระทบด้านงบประมาณเมื่อมีการเปลี่ยนแปลงตัวแปรและสมมติฐานในแบบจำลอง*

ผลการศึกษา: *การเริ่มให้มีการใช้ยา pemetrexed ในโรงพยาบาลทำให้เกิดต้นทุนด้านยาเพิ่มขึ้นอย่างมาก ในแบบจำลองการวิเคราะห์หลักพบว่า ต้นทุนที่เพิ่มขึ้นในปีแรกคือ 8,553,984 บาท และเพิ่มขึ้นเป็น 12,118,144 บาท, 17,820,800 บาท และ 17,820,800 บาท ในปีถัดไป รวมต้นทุนด้านยาที่เพิ่มขึ้นตลอด 4 ปีเป็นเงิน 20,154,480 บาท หรือ ประมาณ 127,560 บาท ต่อผู้ป่วย 1 ราย การวิเคราะห์ความไวพบว่า จำนวนรอบการรักษาและจำนวนของผู้ป่วยที่คาดการณ์ว่าจะต้องได้รับยา pemetrexed เป็นตัวแปรสำคัญที่ส่งผลต่อผลกระทบด้านงบประมาณ*

สรุป: *นวัตกรรมใหม่ที่มีต้นทุนค่าใช้จ่ายสูงควรจะได้รับการประเมินโดยอาศัยการวิเคราะห์งบประมาณก่อน เพื่อพิจารณาว่าจะมีความสามารถจ่ายได้หรือไม่ รัฐบาลไทยควรจะพิจารณากำหนดให้นำเสนอผลการวิเคราะห์งบประมาณเป็นส่วนหนึ่งของกระบวนการยื่นคำขอเกี่ยวกับยาเพื่อใช้สำหรับการพิจารณาข้อเสนอบรรจุยาเข้าสู่บัญชียาและการให้เงินอุดหนุนสำหรับค่ายา*