Drug pricing measures for the reimbursement

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Abstract

Background: There are many effective drug pricing systems which Thai Government should employ to solve drug pricing problems especially at the reimbursement level. This research focuses on a comparison of budget saved by the payer after the application of different drug pricing measures at the reimbursement level.

Methods: This was a quantitative research. The budget impact analysis modeling to estimate the budget saved from the pricing policy implementation was employed.

Drugs belonged to the group HMG-CoA reductase inhibitor (statins) were purposive sampling to be the sample for the budget impact analysis. They were divided into 3 groups and the sample of each group was shown in the bracket: 1) Innovative drug with therapeutic improvement (Rosuvastatin), 2) Innovative drug with technical improvement (Amlodipine+Atorvastatin), and 3) Innovative drug with Generic drug (Atorvastatin).

Drug pricing measures assigned for each drug groups were 1) Price Volume Agreement, 2) Value Based Pricing, 3) Maximum Allowable cost, and 4) Reference pricing.

Results: In terms of budget saving for: 1) Innovative drug with therapeutic improvement group: Reference Pricing measure saved more budget than Price Volume Agreement. 2)) Innovative drug with technical improvement group: Value Based Pricing measure saved more budget than Price Volume Agreement. 3) Innovative drug with Generic drug group: Reference Pricing measure saved more budget than Maximum Allowable Cost.

Discussion: The magnitude of saving in each measure depends on the factors such as percentage of drug rational use, numbers and prices of drugs available in the market, and availability of local made drugs.

Conclusion: There are many effective drug pricing measures which can be used to reduce the reimbursement budget. The government should place the right measure to each drug to gain its most benefit.

Keywords: Drug pricing measures, reimbursement, Price Volume Agreement, Reference Pricing, Maximum Allowable Cost, Value Based Pricing.

บทคัดย่อ วิธีการกำหนดราคายาสำหรับการจ่ายเงินคืน

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มาตรการกำหนดราคาซึ่งมีประสิทธิภาพหลายวิธี ที่รัฐบาลไทยควรเลือกใช้เพื่อแก้ปัญหางบประมาณที่จ่ายในการ คืนเงินค่ายา การวิจัยนี้ต้องการเปรียบเทียบมูลค่าการประหยัดงบประมาณของรัฐบาลเมื่อใช้มาตรการต่างๆในการกำหนด

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ราคาคืนเงินค่ายา การวิจัยทำในรูปแบบเชิงปริมาณและสร้างแบบจำลองเพื่อทำนายงบประมาณที่ประหยัดได้ ยาที่ใช้เป็น ตัวอย่างคือ ยาในกลุ่ม HMG-CoA reductase inhibitor (statins) แบ่งยาออกเป็น 3 กลุ่ม และชื่อยาที่ใช้เป็นตัวอย่าง แสดงในวงเล็บ คือ 1) ยาใหม่ที่ให้ผลการรักษาดีขึ้น (Rosuvastatin), 2) ยาใหม่ที่มีการปรับปรุงเชิงเทคนิค (Amlodipine+Atorvastatin), 3) ยาใหม่ที่มียาชื่อสามัญแล้ว (Atorvastatin). มาตรการกำหนดราคายาที่ใช้ในการวิจัยนี้คือ 1) Price Volume Agreement, 2) Value Based Pricing, 3) Maximum Allowable cost, และ 4) Reference pricing.

ผลการวิจัยแสดงให้เห็นว่า เมื่อมุ่งถึงการประหยัดงบประมาณ 1) กลุ่มยาใหม่ที่ให้ผลการรักษาดีขึ้น มาตรการ Reference pricing ดีกว่า Price Volume Agreement 2) กลุ่มยาใหม่ที่มีการปรับปรุงเชิงเทคนิค มาตรการ Value Based Pricing Value Based Pricing ดีกว่า Price Volume Agreement 3) กลุ่มยาใหม่ที่มียาชื่อสามัญแล้ว มาตรการ Reference pricing ดีกว่า Maximum Allowable Cost ซึ่งการที่แต่ละมาตรการจะก่อให้เกิดการประหยัดงบประมาณ ได้ต่างกันอย่างไรนั้น ขึ้นกับปัจจัยหลายประการเช่นอัตราการใช้ยาที่สมเหตุสมผล จำนวนของยาที่มีในตลาด ราคายาที่ขาย และการมียาที่ผลิต ในประเทศ รัฐบาลควรเลือกมาตรการกำหนดราคาให้เหมาะสมกับยา เพื่อให้เกิดการประหยัดสูงสุด

คำสำคัญ: การตั้งราคายา มาตรการการตั้งราคา การจ่ายเงินคืน การตกลงเรื่องราคากับปริมาณใช้ ราคาอ้างอิง ราคา สูงสุดที่อนุญาต การตั้งราคาตามคุณค่า

Introduction

arious countries including Thailand have faced the increasing burden in health care expenditure mainly caused by the increase in drug spending. Consequently, many of them established the medicine price control policy to encounter the problem. The national health organization set prices of drug to be reimbursed. However, Thailand has not yet developed any drug pricing control measures and policies. Drugs utilized under the Civil Servants' Medical Benefit Scheme (CSMBS) are reimbursed by The Comptroller General's Department of The Ministry of Finance. Major drug pricing problems found at the reimbursement level in Thailand were: variation of purchasing and selling prices of same drug trade names among hospitals, ineffective drug price negotiation for high cost-monopoly innovator drugs (1), and high consumption of expensive innovator drugs. (2,3)

There are many effective drug pricing systems such as International Price Comparison, Risk sharing by Price-Volume Agreement (PVA), Risk sharing by Performance-linked reimbursement, Reference Pricing (RP), Maximum Allowable Cost (MAC) and Value Base Pricing (VBP).

International Price Comparison

International price comparisons for pharmaceuticals are used for 2 primary purposes; price comparisons based on a sample of products are used to draw conclusions about differences in average price levels, often as input to evaluation of alternative regulatory systems for drug prices. Second, cross-national comparisons applied to individual products are used by governments for example, Italy, Spain, The Netherlands and Canada - for setting domestic prices, usually for newly launched products. International price comparisons limited in varies price in other country. (4)

Risk sharing by Price-Volume Agreement

Price Volume Agreement; PVA is drug policy measures and a volume control tool. The price of a pharmaceutical agreed between public authorities and a manufacturer on the basis of a forecast volume of



sales. If the actual sales volume exceeds the forecast, the price of the pharmaceutical is usually reviewed downwards. Particularly useful in situations where unit prices are higher than comparators and there is potential for high prescription volumes, or when there is significant uncertainty about the estimated volumes. (5)

Risk sharing by Performance -linked Reimbursement

This approach is used when a manufacturer agrees to refund the cost of ineffective treatment to the payer. They assume their drug is having benefit outcome on the patients. The payer will pay for only drug that improves health outcome. Risk-sharing is the common practice of tying pharmaceutical reimbursement or recommendation for adoption to health outcome. It can be called in many different ways based on the country in which they are negotiated and/or the companies that undertake them. The most common are value-based pricing, conditional coverage, pay-for-outcomes and performance based pricing. Two factors that encourage the use of risk-sharing are pharmaceutical cost and pharmaceutical quality. (6)

Reference Pricing

Reference Pricing; RP is to set fixed reimbursement limits for products assigned to the same group. In principle, products that treat the same medical condition are clustered together and a judgment made as to what a fair common price would be for all products in the cluster for a typical patient. RP is not strictly a price control mechanism as the pharmaceutical manufacturer is free to set any price for their product. It can intensify price competition among drug in the same cluster. This is an advantage of RP. The

purpose of reference pricing of fixed reimbursement levels is to limit the rise in pharmaceutical expenditure by setting a limit on the price that health care payers will fully reimburse and requiring patients to pay any excess of the price of the prescribed drug over the reference price. (7)

Other issues may also be involved, it is anticipated to increase patient and physician awareness of the prescribed drug's price and possibly result in the patient being switched to a drug listed at the reference price. If switching occurs, then a convergence of drugs in the same category to the reference price generally follows. RP is one of the few available policies likely to be effective at directing prescriber behavior towards the latter approach. Because RP does not influence the factors which relate to increases in the volume of drugs used, it may produce at best, a temporary interruption in the rate of increase of drug prices. In addition, RP forces manufacturers of branded products to choose between two strategies: 1) to reduce prices to bring them in line with the reference price, or 2) to maintain prices above the reference price therefore, capture a brand-premium for its efforts in marketing and sales and eventually for real differences in quality.

A comprehensive review of the publish literature of reference pricing by Lopez-Casasnovas and Puig-Junoy⁽⁷⁾ showed that the prices of products covered by reference pricing tended to decrease, leading to reductions in third-party pharmaceutical expenditure.

Maximum Allowable Cost

Maximum Allowable Cost; MAC is method for establishes maximum reimbursement amounts for

equivalent groups of multiple-source generic drugs. (8) The government has the flexibility to establish their own payment ceilings for multiple source drugs, so long as they do not exceed the federal payment ceiling for Federal Upper Limit (FUL) drugs. Slightly over half the states have taken advantage of this cost containment tool, which would enable them to limit their liability with regard to drug pricing.

The federal government has accepted several state options for calculating the reimbursement to pharmacies for prescriptions for patients. Most use a formula based on the Average Wholesale Price (AWP) reported for each drug to determine reimbursement to pharmacies.

However, when multiple generic equivalent drugs are available, states have the option of using Maximum Allowable Cost (MAC) to set a cap on payment for brand or generic versions of the same drug. States may establish their own MAC to use for reimbursement to pharmacies. Under the MAC formula, states establish a single price for each generic regardless of the manufacturer of the generic. (9)

Value Base Pricing

Value-based pricing is a method of pricing products in which companies first try to determine how much the products are worth to their customers. The goal is to avoid setting prices that are either too high for customers or lower than they would be willing to pay if they knew what kind of benefits they could get by using a product. (10)

The limitations relating to the practical application of VBP for medicines. $^{(10)}$ They include:

 A lack of evaluation of the additional health related benefits of items such as new medicines for conditions like.

- 2) The government is also not presently charged with evaluating the long term external benefits that will in time be generating as a result of, for instance, an improved understanding of cancer genomics and/or the provision of high quality employment in the pharmaceutical sector
- A lack of between best practice developments and the publication of supportive evidence.

Objectives of this study

To compare budget saved by the payer after the application of different drug pricing measures at the reimbursement level.

Methods

Research design

This was a quantitative research. The budget impact analysis modeling to estimate the budget saved from the pricing policy implementation was employed.

Sampling procedure

Drugs belonged to the group HMG-CoA reductase inhibitor (statins) were purposive sampling to be the sample for the budget impact analysis. They were divided into 3 groups and the sample of each group was shown in the bracket:

- 1. Innovative drug with the rapeutic improvement (Rosuvastatin),
- 2. Innovative drug with technical improvement (Amlodipine+Atorvastatin),
- 3. Innovative drug with Generic drug (Atorvastatin).

Drug pricing measures assigned for each drug



groups were 1) Price Volume Agreement, 2) Value Based Pricing, 3) Maximum Allowable cost, and 4) Reference pricing

PVA measure, the reimbursed price were compare percent of benefit rebate to third party payer. The rational were set at 70 percent, then the exceeding 30% of consumption will be reimbursed less; at 50% of original price.

VBP measures, the reimbursed price were compare the price of fixed-dose combination with single original price and single local made price. The benefit were refund at percentage difference of price into government.

MAC measures, The reimbursed price were calculate multiple by rate MAC price. The first lowest price were multiplied with 110%. The second lowest prices were multiplied by 106%. The price were selected on the higher of the two MAC rates price

RP measure, the reimbursement of original drug price instead with local made drug price in same pharmacology. The drug price were calculated from median price divides with Define Daily Dose; DDD of local made drug price.

Data collection

The amount and value of imported drugs in 2010 were collected from the Food and Drug databases. Their drug utilization data in 2010 were retrieved from one teaching hospital databases; data variables included the drug name, strength, dosage form, and drug cost and charge, volume and value of drug utilization according to types of payment scheme as Civil Servants' Medical Benefit Scheme (CSMBS), Universals Coverage (UC), Social Security System (SSS), and Self pay.

Data analysis

An Excel model was constructed for the Budget Impact Analysis in terms of budget saved by the payer after the application of different drug pricing measures at the reimbursement level. The measure that saved most would be recommended.

This price per tablet is available on the website of Center of Essential Information for All Health Officers (DMSIC), http://dmsic.moph/price/price1.php. Only the drugs utilized by CSMBS patients are reimbursed by the Ministry of Finance, so the number of CSMBS patients who used Rosuvastatin, Amlodipine+Atorvastatin, and Atorvastatin during the year 2010 at a teaching hospital were retrieved and calculated as percentage of total consumption of that drug. This percentage was multiplied to total imported or manufactured volume, as retrieved data from the FDA, to be an approximate volume of the national consumption

Results

The considering of Outpatient drug utilization and expenditure of Civil Servant Medical Benefit Scheme, CSMBS found that total drug utilization percentage all drug groups in CSMBS scheme show that atorvastatin (76.87% or 2902.04 M.baht), and rosuvastatin (77.69% or 1144.41 M.baht) of group were drug with the highest drug expenditure percentage in HMG co A inhibitor group

Pricing measures for innovative drugs with therapeutic improvement.

Rosuvastatin was selected as the sample. In the year 2010, Rosuvastatin was imported 1,473 M. baht, or 33,869,052 DDD (43.49 baht/DDD). Consump-

tion of this drug by CSMBS patients at a teaching hospital was 77.69%; so approximately 1144.41 M.baht were consumed by CSMBS patients at the national level which will be reimbursed. Two pricing measures will be applied as:

1.1 Risk sharing by Price-Volume agreement.

The volume of drug used rationally will be fully reimbursed. The exceeding consumption will be reimbursed at a downward negotiated price. Let's set the example of Rosuvastatin's rational use at 70%, then the exceeding 30% of consumption will be reimbursed less; at 50% of original price. Therefore 30% consumption or 343.32 M.baht will be reimbursed at 171.16 M.baht instead of 343.32 M.baht. So the government will save 171.66 M.baht or 15 % (171.66 M.baht × 100/1144.41 M.baht.) by Price-Volume agreement. But if the government decides not to reimburse for the irrational use portion, then 343.32 M.baht will be saved.

1.2 Reference pricing

By this measure Rosuvastatin will be reimbursed at the price of lowest generic drug in the same therapeutic group which should be Atorvastatin. The price of Atorvastatin is 17.79 baht./DDD compared to Rosuvastatin at 43.49 baht/DDD. Then Rosuvastatin will be reimbursed at 17.79 baht./DDD or saved by 59.09%. When this figured is calculated as national consumption, it will save 676.28 M.baht.

2. Pricing measures for innovative drugs with technical improvement.

Amlodipine+Atorvastatin was selected as the sample. In the year 2010, Amlodipine+Atorvastatin was imported 290.0 M.baht, or 3,678,150 DDD (79.0 baht/DDD). Consumption of this drug by CSMBS patients at a teaching hospital was 79.5%; so approxi-

mately 230.48 M.baht were consumed by CSMBS patients at the national level which will be reimbursed. Two pricing measures will be applied as:

2.1 Risk sharing by Price-Volume agreement.

The volume of drug used rationally will be fully reimbursed. The exceeding consumption will be reimbursed at a downward negotiated price. Let's set the example of Amlodipine+Atorvastatin rational use at 70%, then the exceeding 30% of consumption will be reimbursed less; at 50% of original price. Therefore 30% consumption or 69.17 M.baht will be reimbursed at 34.58 M.baht instead of 69.17 M.baht. So the government will save 34.58 M.baht or 15% (34.58 M.baht × 100/230.55 M.baht.) by Price-Volume agreement.

2.2 Value Based pricing When 2 singular drugs are reformulation as a fixed-combination drug and registered as an innovative drug but shows no therapeutic improvement when compared with the co-administration of each single agent, the price of this fixed-combination drug should not exceed the summation of each single agent. In this example fixed combination of Amlodipine 10 mg +Atorvastatin 40 mg are priced 85.00 baht (11), while single Amlodipine 10 mg is 1.41 baht. and Atorvastatin 40 mg is 37.23 baht from the website of DMSIC. The price of this fixed combination should not be more than 38.64 baht. And the therapeutic efficacy of the combination drug is not better than co-administration of each single agent. (12,13) Thus the reimbursement price should be 38.64 baht. not 85.00 baht., and the government will save 46.36 baht. per tablet or 54.54%

Pricing measures for innovative drugs with generic drugs

When innovative drugs were off-patent, im-



ported an d local made generics would enter the market. This part illustrates the Reference Pricing measure and Maximum Allowable Cost pricing measures for reimbursement. Atorvastatin 40 mg is the example of this group. In the year 2010 Atorvastatin 40 mg was imported 728.16 M.baht. or 12,161,720 tablet (59.87 baht./tablet), 76.87% were consumed by CSMBS patients, or approximately 559.71 M.baht at the national level which will be reimbursed. Two pricing measures will be applied as:

3.1 Reference Pricing: By this measure innovative Atorvastatin 40 mg will be reimbursed at the price of lowest generic drug in the same therapeutic group which should be Simvastatin 40 mg.

The price of Simvastatin 40 mg is 1.13 Baht./tablet compared to Atorvastatin 40 mg at 59.87 baht/tablet. Then Atorvastatin will be reimbursed at 1.13 baht. or saved by 58.74 baht./tablet or 98.11%. When this figured is calculated as national consumption, it will save 549.13 M.baht.

3.2 Maximum Allowable Cost (MAC): Average prices for 3 available brands of Atorvastatin 40 mg were 50.29 baht., 37.23 baht., and 29.00 baht.; calculated MAC was 39.46 baht./tablet.* As compared to average imported Atorvastatin 40 mg at 59.87 baht/tablet. Then Atorvastatin 40 mg will be reimbursed at 39.46 baht/tablet or saved by 20.41 baht./tablet, or 34.09%. When this figured is calculated as

Table 1 Comparison of value (Million baht.) and % saved for the government by application of each pricing measure at the reimbursement.

	Drug classification		
	1.Innovative drugs with therapeutic improvement	2. Innovative drugs with technical improvement	3. Innovative drugs with generic drugs
Sample	Rosuvastatin	Amlodipine+Atorvastatin	Atorvastatin 40 mg
Value imported (M.baht.)	1,473.00	290.00	728.16
% consumed by CSMBS	77.69	79.50	76.87
Value consumed by CSMBS	1,144.41	230.55	559.71
Value, M.baht. (% saved) for the governmen	t by each pricing measu	re	
- Risk sharing by Price-Volume agreement	171.16	34.58	
	(15%)	(15%)	
- Value Based pricing		125.64	
		(54.54%)	
- Reference Pricing	675.20		549.13
	(59.09%)		(98.11 %)
- Maximum Allowable Cost			190.81
			(34.09%)

^{*}Calculation: First MAC rate price = first lower price \times 1.1 = 29 \times 1.1 = 31.9 baht. Second MAC rate price = second lower price \times 1.06 = 37.236 \times 1.06 = 39.46 baht.

So the reimburse price by MAC rate will be 39.46 baht.; because this rate is higher than the first and second lower prices.

national consumption, it will save 190.81 M.baht.

Table 1 shows the summary result of each measure. It was found that the Reference Pricing measure is the most budget saving at the reimbursement level.

Discussion

It is impossible to point out which measure will best for each drug because of different pattern of drug utilization and drug prices in the market. When compared between Price-Volume agreement (PVA) and Reference Pricing (RP), the magnitude of budget saved by PVA depends on the percentage of rational use and the percentage of price reimbursed for drug used irrationally; while the magnitude of budget saved for RP depends on the prices of generic drugs in the market. For PVA, if the percentage of irrational use is very high then the budget saved from price reduction of irrational use drug will be high; and if the percent reimbursed of irrational use drug is low then the budget saved will be high. For RP, if the price of a drug used as reference is not much cheaper than the original one then the budget saved will not be much. There was not any study revealed the percentage of drug rational use, so this rate used in this study was set up. Application of the PVA measures needs a reliable rate of drug rational use.

Regarding the Value Based pricing, it is important to keep in mind about the efficacy of drugs and the prices, this measure should be used when there are enough document to prove the efficacy of single drug and combined drugs.

When there are many brands in the market the Maximum Allowable Cost (MAC) measure will pro-

vide reasonable reimbursed prices for the manufactures of generic drugs because it is not based on the lowest price in the market.

The magnitude of saving in each measure depends on the factors such as percentage of drug rational use, numbers and prices of drugs available in the market, and availability of local made drugs.

In the case of Rosuvastatin, the budget saved from RP is higher than PVA because we set the pricing model as 70% rational use and reimbursed 50% of those with irrational use. If the percentage of rational use was 10% and no reimbursement for irrational use, then the amount of budget saved would be much higher. For RP, the prices of generic reference drugs are very cheap, thus the budget saved is high. The application of RP measure may cause patients to copay if they want to use original drugs or premium generic drugs. For fixed combination drug like 'Amlodipine+Atorvastatin' it is not possible to use RP measure but Value Based pricing is preferable.

Limitation of study

There might be some other effective pricing measures which are not mentioned here, so they should be thoroughly explored before selecting an appropriate one.

Conclusion and recommendations

In terms of budget saving for: 1) Innovative drug with therapeutic improvement group: The Reference Pricing measure saved more budget than Price Volume Agreement. 2) Innovative drug with technical improvement group: The Value Based Pricing measure saved more budget than Price Volume Agree-



ment. 3) Innovative drug with Generic drug group: The Reference Pricing measure saved more budget than Maximum Allowable Cost.

This study shows that there are many effective drug pricing measures which can be used to reduce the government's reimbursement budget. The government should place the right measure to each drug to gain its most benefit. There should be an office that provides information regarding drug use pattern and market pattern for the organization to use as input for the reimbursement purpose.

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