



## Monitoring of the Implementation of Non-Essential Drug Prescribing Criteria Measure in Case of Anti-Osteoporosis Drugs

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**Background and objective:** In the 2013 fiscal year, the Comptroller General's Department (CGD), Thailand, had launched the Non-essential Drug Prescription Criteria (NPC) measure for high cost non-essential drug (NED) to encourage the rational drug use and control drug cost for patients under the Civil Servant Medical Benefit Scheme (CSMBS). This study aimed to evaluate the implementation of the NPC measure in the prescription of non-essential drugs in the anti-osteoporosis group.

**Methods:** This retrospective study was performed by gathering the information about NPC measure from the electronic database and detail about clinical presentation or drug utilization supporting the use of NED from the medical records of the out-patients under CSMBS who received NED in anti-osteoporosis group at Srinagarind Hospital between August 1st and

September 30th, 2014. Data were analyzed by descriptive statistics.

**Results:** There were 463 patients recruited into the study. Patients were mainly female (94.2%) and aged over 65 (70.2%). The three highest prescribing drugs were alendronate plus cholecalciferol (41.7%), risedronate (22.9%) and ibandronate (11.0%). The most specified NPC was item C (76.5%), followed by item B (17.7%) and item A (4.7%). No detail about clinical presentation or drug utilization supporting the use of non-essential drug instead of essential drug (ED) was documented in the medical records.

**Conclusions:** Prescribing anti-osteoporosis drugs for the out-patients under CSMBS was generally complied with the NPC measure but the consistency between information in the electronic database and medical records could not be assessed.

**Keywords:** non-essential drug, anti-osteoporosis drug

ศรินทรินทร์เวชสาร 2559; 31 (suppl): 102-4. ♦ Srinagarind Med J 2016; 31 (suppl):102-4.

### Introduction

Irrational use of medicine has been a dramatic problem worldwide and caused money wasting that affected either health systems or public health budgets. The World Health Organization (WHO) reported that the problem of irrational drug use was up to 50% of all prescriptions<sup>1</sup>. In Thailand, previous study also reported

that money spending for drug expenditure had been increased steadily especially in patients with Civil Servant Medical Benefit Scheme (CSMBS) employing open-ended provider payment method. An analysis of prescriptions and drug expenditures of out-patient using the direct billing system in 26 large public hospitals during July 2011 to March 2012, revealed that 41% of total

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prescriptions and 67% of drug expenditures belonged to the drugs beyond the Thai National List of Essential Drugs. Using of non-essential drugs (NED) which were expensive or in high volume, may affect the overall cost. For bisphosphonates, the main drug for treating osteoporosis, the number of prescription was not large but the cost of drug was very expensive. Money spending for treating osteoporosis in 2012 was about 570 million baht and accounted for about 5% of total drug expenditure<sup>2</sup>. As the proportion of NED in this drug group was about 98%, the Comptroller General's Department (CGD), Thailand, had launched the measure for controlling prescriptions of anti-osteoporosis since fiscal year 2011<sup>3</sup>, which was specified as Non-essential Drug Prescription Criteria (NPC) measure in the fiscal year 2013<sup>4</sup>.

The aim of the present study was to monitor the implementation of the NPC measure in prescribing drugs of the anti-osteoporosis group.

### Methods

The retrospective study protocol was approved by the Khon Kaen University Ethics Committee for Human Research (HE571462). Samples were prescriptions and medical records of outpatients under CSMBS who received NED of anti-osteoporosis group from 1 August to 30 September 2014. Prescribed drug data were collected and classified according to the NPC as A-F drug items (adverse drug reaction or allergy occurred, A; the treatment cannot be accomplished, B; no essential drug available and the patient need non-essential drug usage indicated by Food and Drug Administration, C; patient has contraindication or drug interaction with the essential drugs, D; essential drug is more expensive when considering worthiness aspect, E; in case the patient shows his intention and the reimbursement cannot be completed, F) in prescriptions. Specified reasons provided by physicians in the patient medical records why NEDs instead of EDs were selected, would be collected as well. Other data that may support NED prescribing such as physical examination and laboratory investigations were also collected. The consistency of rational reasons to prescribe the anti-osteoporosis drugs from the prescription data and the patient medical records were compared. All data were

quantitatively analyzed using descriptive statistics as number of frequency and percentage.

### Results

NEDs of anti-osteoporosis group were prescribed in 588 patients. However, data from medical records could not be achieved in 125 patients so that only 463 patients were recruited into the study. Patients were mainly female (94.2%) and over 65 years of age. The drug preparation containing alendronate plus cholecalciferol was most prescribed (41.7%) as shown in Table 1. The most specified NPC was item C (76.5%), followed by item B (17.7%) and item A (4.7%) as shown in Table 2. However, as no data supporting the use of NED was found in the patient medical records, the consistency of implying the NPC could not be assessed in all prescriptions.

### Discussion

From the total 463 patients in the present study, 94.2% were female and 70.2% were over 65 years of age, which are the 2 major risk factors of osteoporosis. The peak bone density is achieved early in the third decade of life (early 20s). Although peak bone densities are similar in men and women, men have about 10-12% greater peak bone mass and bone size so that the incidence of osteoporotic fracture in male is lower than female, but the mortality rate after fracture is higher for men. The age at which bone loss begins may differ among skeletal sites and is certainly seen after 50 years of age in both men and women. In elderly, bone mass is not increased; meanwhile, the bone loss is still

Table 1 Patients' characteristics

Characteristic	Number of patient (%)
Female	436 (94.2)
Age over 65 year old	325 (70.2)
Drug name	
Alendronate	22 (4.7)
Alendronate plus cholecalciferol (2800IU)	193 (41.7)
Ibandronate	51 (11.0)
Risedronate	106 (22.9)
Zoledronic acid	24 (5.2)
Teriparatide	3 (0.7)
Raloxifene	19 (4.1)
Strontium ranelate	45 (9.7)

**Table 2** Non-essential drug (NED) prescribing criteria indicated for each prescription

Drug name	Number of patient (%)					
	A	B	C	D	E	F
Alendronate	1	3	17	-	-	1
Alendronate plus cholecalciferol (2800IU)	11	38	142	2	-	-
Ibandronate	3	5	43	-	-	-
Risedronate	5	25	75	1	-	-
Zoledronic acid	1	2	21	-	-	-
Teriparatide	-	1	2	-	-	-
Raloxifene	1	-	18	-	-	-
Strontium ranelate	-	8	36	1	-	-
<b>Total</b>	<b>22 (4.7)</b>	<b>82 (17.7)</b>	<b>354 (76.5)</b>	<b>4 (0.9)</b>	<b>-</b>	<b>1 (0.2)</b>

progressed due to osteoclast-mediated bone resorption, endocortical thinning and increased cortical porosity especially when the patients become menopausal stage and estrogen deficiency. Estrogen-deficient bone loss initially occurs at a faster rate than other age-related causes of bone loss<sup>5</sup>.

From the study, item C was the highest NPC (76.5%) because only 2 anti-osteoporosis drugs are included in category D of the Thai National List of Essential Drug. The first drug was calcitonin salmon injection which produces uncertain efficacy in treating osteoporosis and is indicated in patient with acute pain after bone fracture or patient with severe hypercalcaemia. Moreover, the surveillance for cancer risk should be performed with calcitonin use<sup>6,7</sup>. The other drug is pamidronate injection which is indicated for treating hypercalcaemia in cancer patients. However, no detail about clinical presentation or drug utilization supporting the use of non-essential drug instead of essential drug was provided in the medical records so that the consistency between data indicated in the electronic database and medical records could not be assessed.

### Conclusion

Prescribing anti-osteoporosis drugs for the out-patients under CSMBS was generally complied with the NPC measure. However, the consistency between data indicated in the electronic database and medical records could not be assessed because of the lacking of detail about clinical presentation or drug utilization supporting the use of non-essential drug in the medical records.

### Acknowledgements

We thank Miss Kanokporn Mongkolkul and Miss Ketmanee Sae-Ueng, Faculty of Pharmaceutical Sciences, Khon Kaen University for their help in data collection.

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