

Yiling Tsai\*, MBA, PhD<sup>1</sup>, , Pei-Ling Tsai, B.B.A.<sup>2</sup>, Yi-Shan Luo, B.B.A.<sup>2</sup>, Fen-Yu Lin, B.B.A.<sup>2</sup>

<sup>1</sup> Assistant Professor, National Taipei University of Nursing and Health Sciences, Taipei, Taiwan. <sup>2</sup> National Taipei University of Nursing and Health Sciences, Taipei, Taiwan

## INTRODUCTION

Rising global drug prices and constrained NHI budgets in Taiwan highlight the need for fair, transparent reimbursement policies. There are several survey addressing decision makers’ review principles<sup>1,2,3</sup>. However, the relevant real-world evidence is paucity.

## OBJECTIVES

- To explore the association between drug characteristics and NHI reimbursement decisions.
- To assess factors influencing time to reimbursement.
- To assess factors influencing the price ratio between the manufacturer-proposed price and NHI approved price.

## METHODS

This retrospective cross-sectional study analyzed new drug cases reviewed by the NHI between 2019 and 2023. Data sources : publicly available PBRs (Pharmaceutical Benefit and Reimbursement Scheme Joint committee) meeting records and official HTA reports.

### Independent variables:

Category	Variables
Overall clinical benefit	drug innovation classification(Categories 1, 2A, 2B)
Economic value	financial impact 1 <sup>st</sup> -year projections
	financial impact 5 <sup>th</sup> -year projections
	the ratio of Taiwan NHI-approved price (P <sub>T</sub> ) to international median (P <sub>M</sub> )
	the ratio of Taiwan NHI-approved price (P <sub>T</sub> ) to international lowest prices (P <sub>L</sub> )
Disease burden	size of population
	ATC code

### Dependent variables :

1. **Reimbursement approval** (yes/no)
2. Regulatory-to-Reimbursement Interval (**RRI**): days from regulatory approval to NHI coverage.
3. Negotiation Price Ratio (**NPR**): the price ratio between manufacturer-proposed prices and NHI approved price

•**Data analysis:** Descriptive statistics, one-way ANOVA, Pearson correlation, and logistic regression were performed.

## RESULTS

Between 2019 and 2023, 138 new drug cases were reviewed by the NHI, with 136 cases (**98.6%**) ultimately granted reimbursement. 98.6% of PBRs cases were approved, likely because rejections occurred earlier at non-public expert meetings, limiting analysis of how drug characteristics influence NHI decisions. The average RRI was **925 days** (SD = 954), with a median of **645 days**, indicating considerable variability in time to NHI coverage after regulatory approval. The average NPR was **0.90** (SD=0.16), with a median of **0.98**.

Table 1. Included case characteristics

	N=138 (100%)
Drug innovation classification	
Category 1	20 (14.5%)
Category 2A	64 (46.4%)
Category 2B	54 (39.1%)
ATC code	
L01 (Antineoplastic agents)	45 (32.6%)
L04 (Immunosuppressants)	16 (11.6%)
J05 (Antivirals for systemic use)	14 (10.1%)
others	63 (45.7%)
Average (SD) million NTD	
1 <sup>st</sup> -year financial impact projection	57 (147.45)
5 <sup>th</sup> -year financial impact projection	81.7 (209.3)
Average (SD)	
P <sub>T</sub> /P <sub>M</sub>	0.79 (1.88)
P <sub>T</sub> /P <sub>L</sub>	0.89 (0.32)
Average (SD) person	
Size of population	5836 (23726)

Table 2. Pearson Correlation Matrix with Significance

Variable	1st-year financial impact	5th -year financial impact	PT/PM	PT/PL	Size of population	RRI	NPR
1st-year financial impact	1	0.82***	-0.03	0.1	-0.08	0.04	0.19*
5th-year financial impact		1	-0.07	0.07	-0.08	0.13	0.20*
PT/PM			1	-0.05	-0.03	-0.06	-0.11
PT/PL				1	-0.06	-0.13	0.17
Size of population					1	0.05	0.04
RRI						1	0.07
NPR							1

Figure 1. Multivariable Linear Regression for RRI

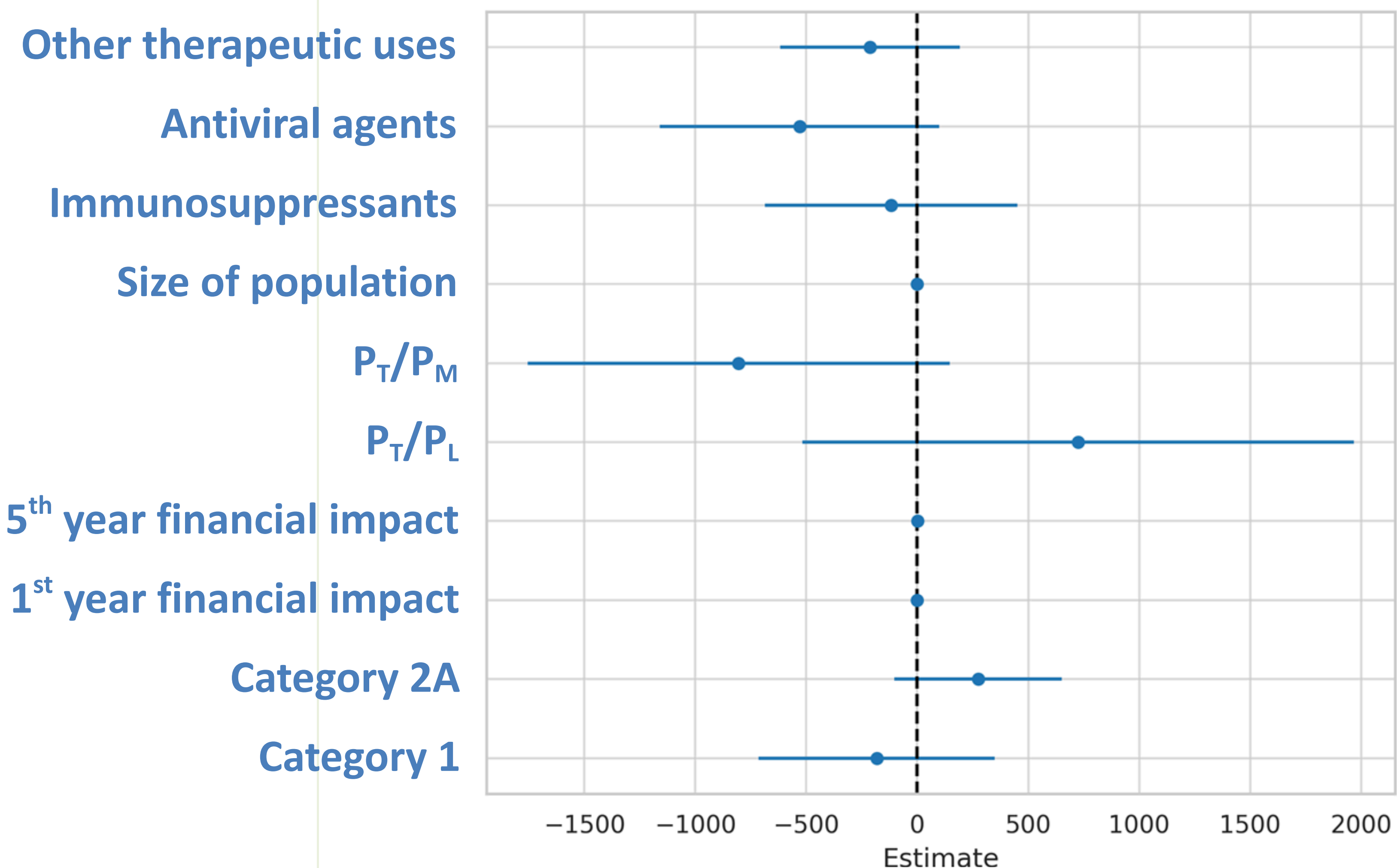
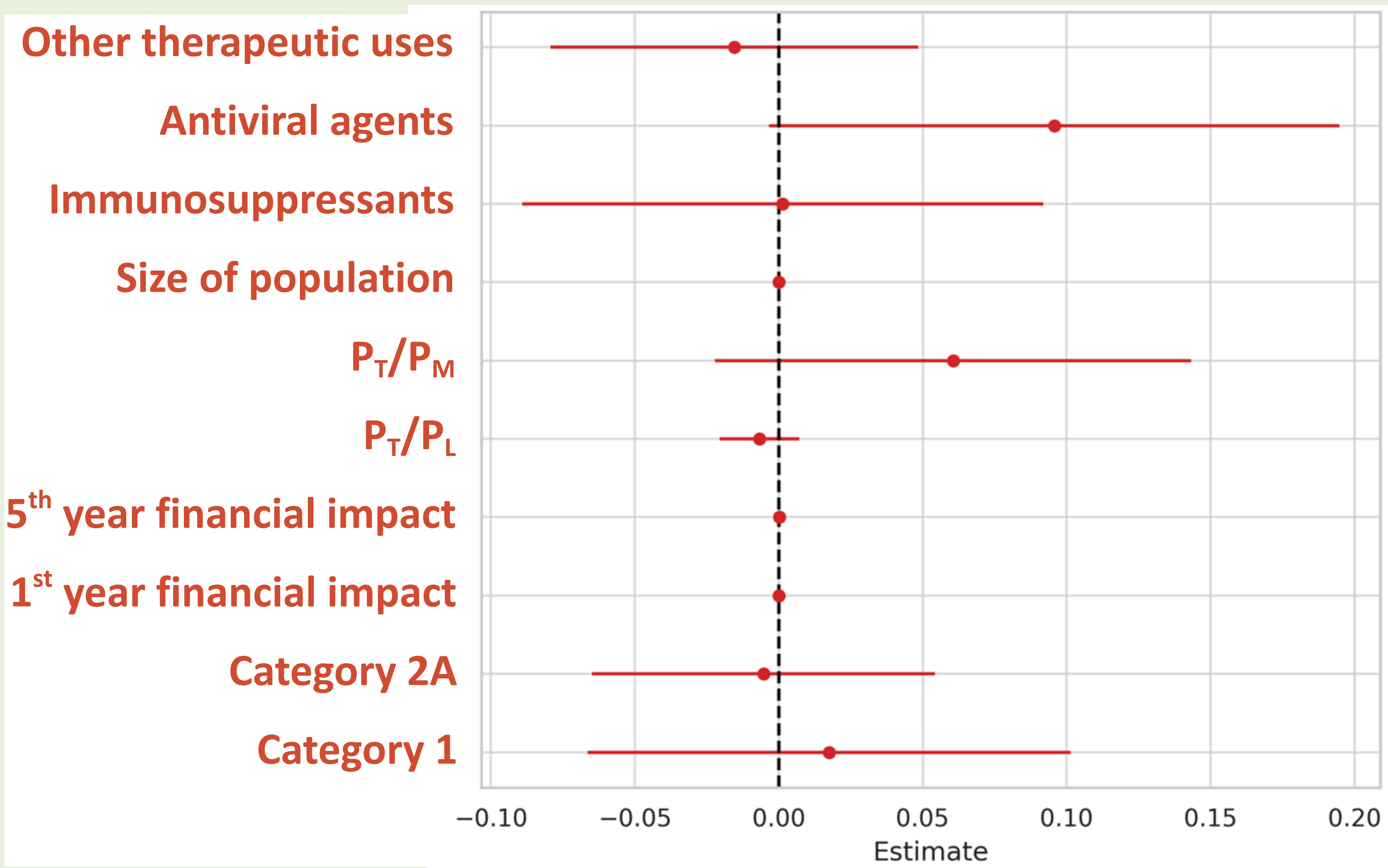


Figure 2. Multivariable Linear Regression for NPR



No significant predictors were identified, but financial and therapeutic factors showed suggestive trends.

## CONCLUSION

NHI reimbursement decisions in Taiwan appear to be based on multifactorial considerations that extend beyond measurable drug characteristics such as innovation class, financial impact, or price comparisons. While most new drugs were ultimately reimbursed, the lengthy reimbursement timeline may hinder timely patient access. To improve transparency and efficiency, the study recommends refining pricing principles, improving data completeness, and considering additional qualitative and policy-level factors in future evaluations.

## REFERENCE

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