

# COST-EFFECTIVENESS OF MIROGABALIN IN TREATMENT OF DIABETIC PERIPHERAL NEUROPATHIC PAIN IN MAINLAND CHINA

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## INTRODUCTION

- Diabetic peripheral neuropathic pain (DPNP) is a chronic microvascular complication of diabetes mellitus associated with debilitating pain, high morbidity, and poor quality of life, which is also a common cause of non-traumatic amputations and hospital admissions as well as increased health-related costs [1].
- Management of DPNP consists of medications and physical therapies to relieve pain. The first-line recommended medications in China include the gabapentinoid anticonvulsants (e.g., pregabalin, gabapentin), TCAs (e.g., amitriptyline), SNRIs (e.g., duloxetine, venlafaxine) [2]. However, DPNP continues to represent a therapeutic challenge as pain relief is still unsatisfactory and limited by side effects and durability [3].
- Mirogabalin, a potent and selective alpha-2-delta ligand for the treatment of DPNP, has shown a substantial and sustained analgesic effect with favorable safety profile [3].

## OBJECTIVES

The objective of this study was to compare the cost-effectiveness of mirogabalin with pregabalin in patients with DPNP from the healthcare system perspective in mainland China.

## METHODS

- A Markov model was implemented, with health states defined as ‘mild’ (weekly average daily pain score (ADPS) < 4), ‘moderate’ (4 ≤ ADPS < 7), and ‘severe’ (7 ≤ ADPS ≤ 10) pain (**Figure 1**). The time horizon was one year with the model cycle of two weeks. At the end of each cycle, patients could remain in their assigned health state or transition to a different health state according to the change in their pain scores or withdraw due to adverse events (WDAE).
- Transition probabilities between health states and probability of discontinuation were informed by an internal network meta-analysis (NMA) comparing mirogabalin and pregabalin (**Table 1**).
  - For short term (0-14 weeks), the weekly ADPS and standard deviation (SD) at baseline and each cycle was converted into transition probabilities using a Monte Carlo simulation. The relative risk (RR) of WDAE was reported in NMA.
  - In the absence of ADPS long term data, long-term transition probability was extrapolated beyond week 14.

Specifically, patients with improvement pain state during the first 14 weeks would stay on treatment, with the week 12 -14 transition probability carrying over. For those who did not improve their pain state during the first 14 weeks, they were assumed to discontinue the treatment and return to their baseline health state. The long-term probability of WDAE was informed by the WDAE for patients treated with mirogabalin as reported in the long-term extension study.

- Cost inputs for drug acquisition costs, health resource utilization and usual care (off treatment) costs were estimated from literature, public government documents, and physician interviews (**Table 2**).
- Utility inputs for each health state were derived from literature (**Table 2**).
- Univariate and probabilistic sensitivity analyses were performed.

Figure 1 Study design and model structure

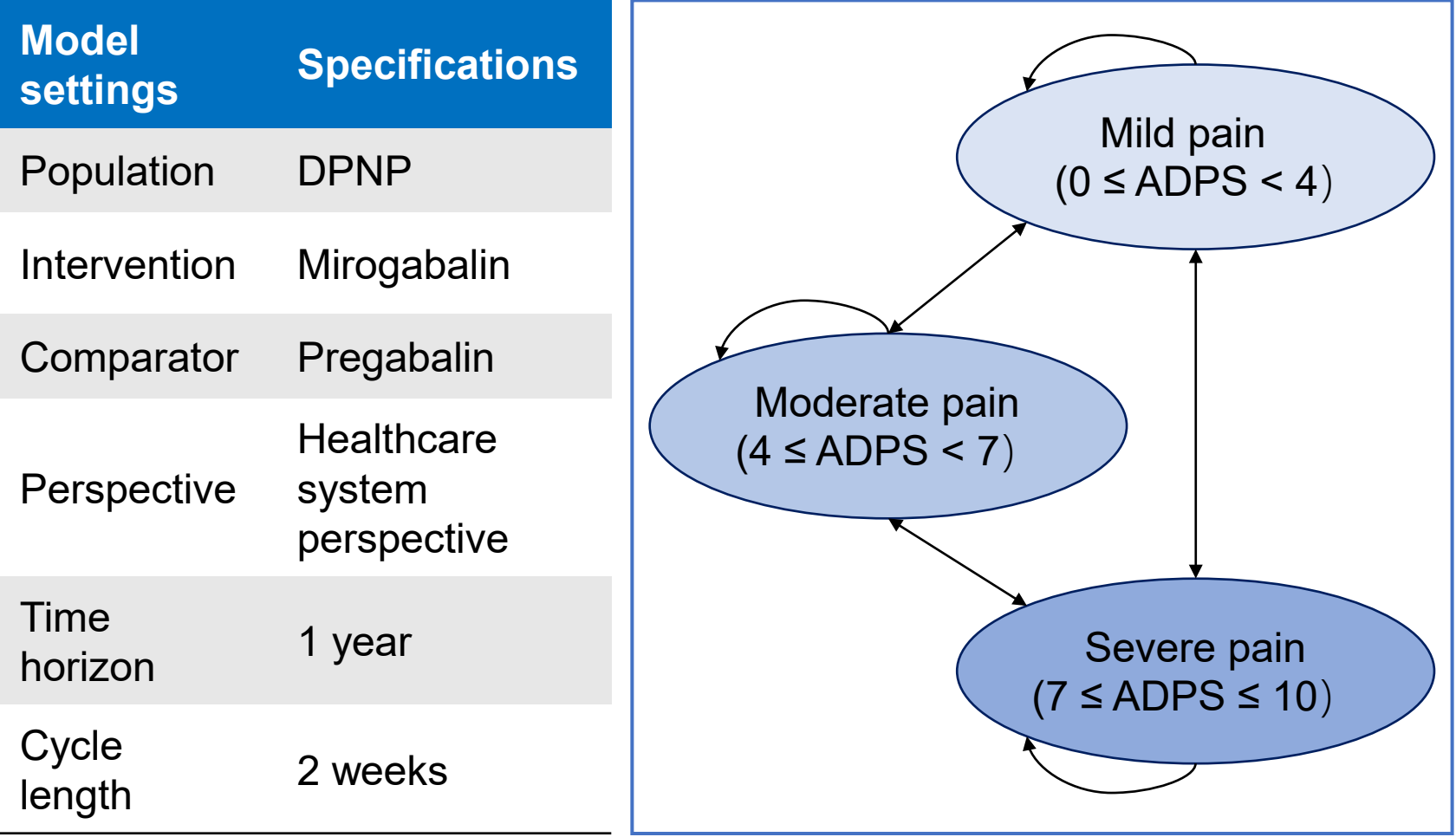


Table 1 Short-term transition probabilities (week 0-14)

MIRO	From\to →	Mild	Moderate	Severe
Week 0-2	Mild	0.00	0.00	0.00
	Moderate	0.26	0.74	0.00
	Severe	0.00	0.54	0.46
Week 2-4	Mild	1.00	0.00	0.00
	Moderate	0.16	0.84	0.00
	Severe	0.00	0.36	0.64
Week 4-6	Mild	1.00	0.00	0.00
	Moderate	0.08	0.92	0.00
	Severe	0.00	0.04	0.96
Week 6-8	Mild	1.00	0.00	0.00
	Moderate	0.06	0.94	0.00
	Severe	0.00	0.12	0.88
Week 8-10	Mild	1.00	0.00	0.00
	Moderate	0.07	0.93	0.00
	Severe	0.00	0.07	0.93
Week 10-12	Mild	1.00	0.00	0.00
	Moderate	0.09	0.91	0.00
	Severe	0.00	0.19	0.81
Week 12-14	Mild	1.00	0.00	0.00
	Moderate	0.09	0.91	0.00
	Severe	0.00	0.17	0.83

PGB	From\to →	Mild	Moderate	Severe
Week 0-2	Mild	0.00	0.00	0.00
	Moderate	0.24	0.76	0.00
	Severe	0.00	0.49	0.51
Week 2-4	Mild	1.00	0.00	0.00
	Moderate	0.15	0.85	0.00
	Severe	0.00	0.32	0.68
Week 4-6	Mild	1.00	0.00	0.00
	Moderate	0.06	0.94	0.00
	Severe	0.00	0.01	0.99
Week 6-8	Mild	1.00	0.00	0.00
	Moderate	0.07	0.93	0.00
	Severe	0.00	0.13	0.87
Week 8-10	Mild	1.00	0.00	0.00
	Moderate	0.06	0.94	0.00
	Severe	0.00	0.07	0.93
Week 10-12	Mild	1.00	0.00	0.00
	Moderate	0.09	0.91	0.00
	Severe	0.00	0.14	0.86
Week 12-14	Mild	1.00	0.00	0.00
	Moderate	0.09	0.91	0.00
	Severe	0.00	0.10	0.90

Abbr.: MIRO=Mirogabalin; PGB=Pregabalin

Table 2 Cost and utility inputs

Key parameters	Source
Costs/per cycle	
Out-patient visit cost -mild/moderate/sever pain	
Lab test cost -mild/moderate/sever pain	Physician interviews
Radiological test costs -mild/moderate/sever pain	Public government documents
Out-patient visit cost - off treatment	
Lab test cost - off treatment	
Radiological test costs - off treatment	
Utility	
Health state utility - mild pain	
Health state utility - moderate pain	Tarride et al. 2006 [4]
Health state utility - severe pain	

## RESULTS

- Base case results**
- Our findings suggested that compared with pregabalin 300mg, mirogabalin was cost-effective with an ICER of CNY 49,057/QALY (**Table 3**). which it is well below the willingness-to-pay threshold of 1 times GDP per capita in China (CNY 80,976).

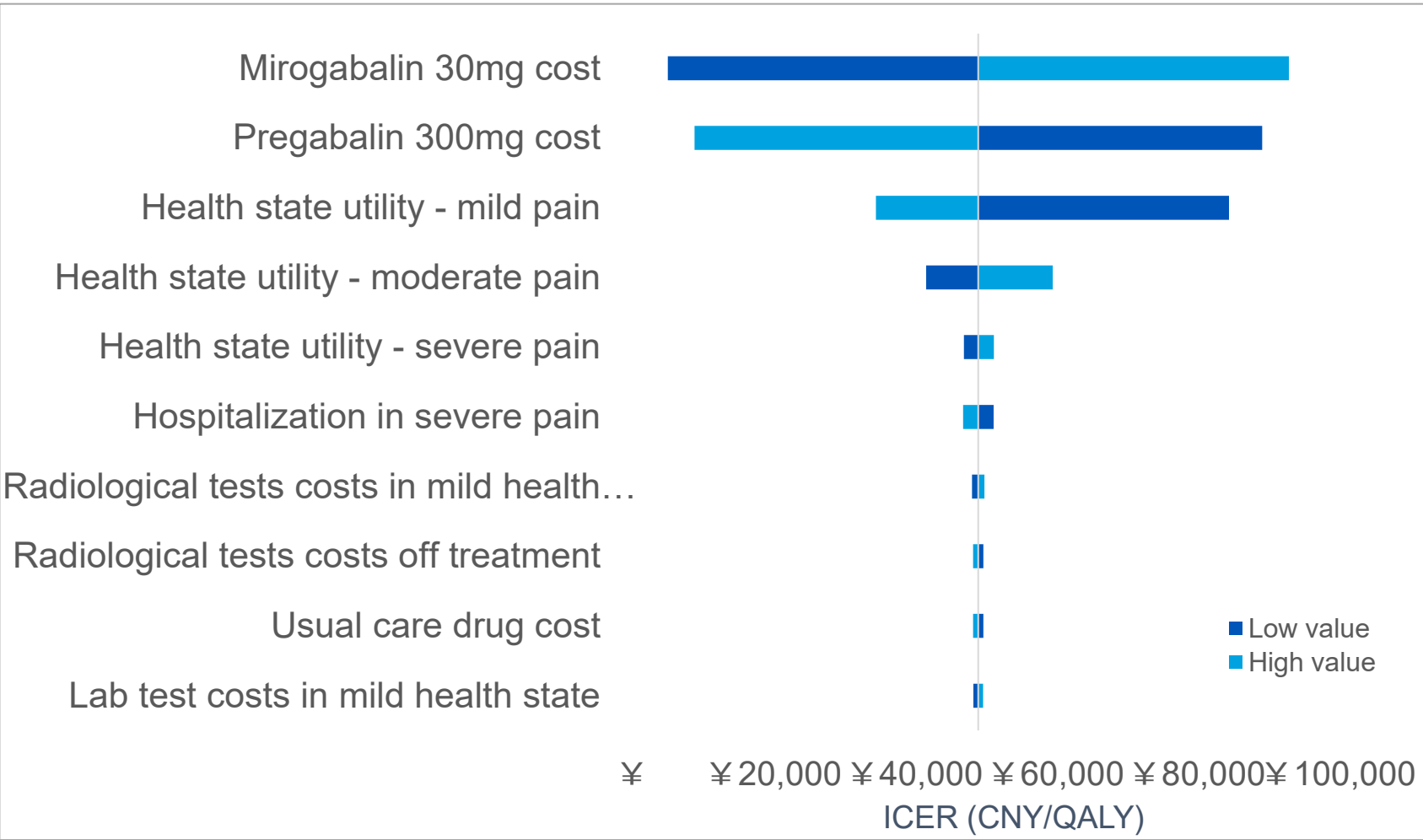
Table 3 Base case results, mirogabalin vs. pregabalin

	Mirogabalin 30mg	Pregabalin 300mg	Incremental
Total costs	CNY 14,699.81	CNY 14,262.87	CNY 436.94
Total QALYs	0.5733	0.5644	0.0089
ICER	/	/	CNY 49,057.42

Abbr.: QALY=Quality adjusted life year; ICER=Incremental cost-effectiveness ration

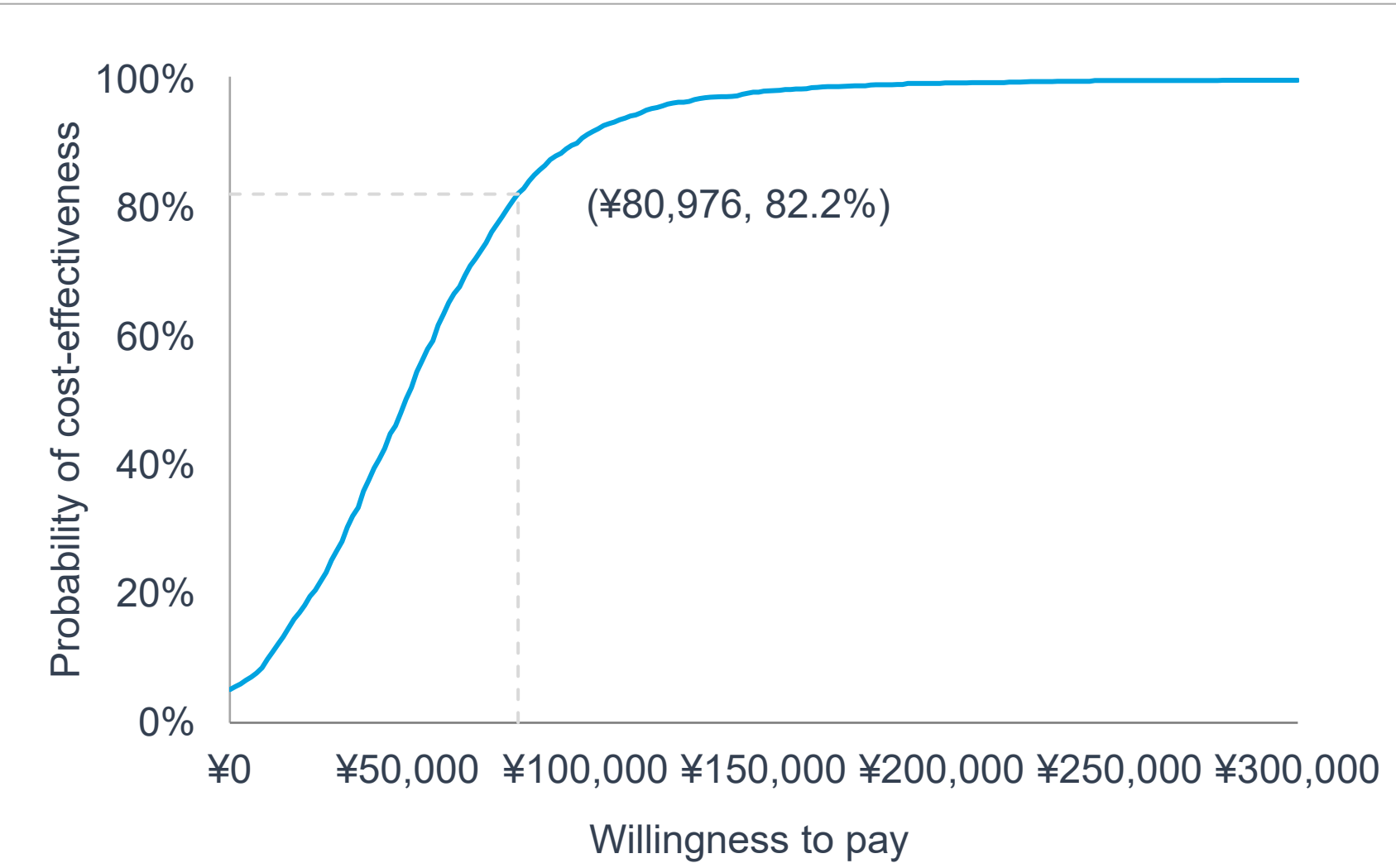
- One-way sensitivity analysis (OWSA)**
- The OWSA has shown that drug costs of mirogabalin, drug costs of pregabalin and health state utility of mild pain had the greatest impact of the model result (**Figure 2**).

Figure 2: OWSA tornado diagram



- Probability sensitivity analysis**
- Sensitivity analysis results demonstrated the robustness of the results, with 82.2% of simulations confirming the cost-effectiveness of mirogabalin (**Figure 3**).

Figure 3: Cost-effectiveness acceptability curve



## CONCLUSIONS

The findings of this economic evaluation has suggested that mirogabalin 30mg, a potent and selective alpha-2-delta ligand, is a cost-effective treatment option for the management of diabetic peripheral neuropathic pain in mainland China.

## DISCLOSURE

This project was sponsored by Daiichi Sankyo, Inc. Funding was not contingent upon publication of the study. Yunzhen He, He Xu, Min Jin and Yuan Feng are current employees of IQVIA. Dong Dai and Rohan Vashi are employees of Daiichi Sankyo, Inc. All the other authors declare that they have no competing interests.

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