

# Budget Impact Analysis of Metreleptin in Patients with Lipodystrophy in Saudi Arabia

Almuaiter A<sup>1</sup>, Alnajjar A<sup>1</sup>, Alrasheed L<sup>1</sup>, Alyami F<sup>1</sup>, Al-Omar H<sup>2</sup>

<sup>1</sup>Ministry of Health (MOH), Riyadh, Saudi Arabia, <sup>2</sup>Department of Clinical Pharmacy, College of Pharmacy, King Saud University, Riyadh, Saudi Arabia.



## INTRODUCTION

- Lipodystrophy (LD) comprises a heterogeneous group of disorders characterized by generalized (GL) or partial (PL) lack of adipose tissues.
- It is classified as an ultra-rare disease which associated with potentially serious complications, including but not limited to, diabetes mellitus, hypertension, dyslipidemia, and hepatic steatosis.
- The global prevalence of LD is estimated to range between 1.3 and 4.7 cases per million. However, the prevalence and economic burden of LD in Saudi Arabia remain unknown.
- Unfortunately, there is no curative treatment for LD, therefore, the current standard of care consists of lifestyle modifications and using therapeutic interventions to manage metabolic conditions associated with LD.
- Metreleptin, a leptin analog, is a pharmacological intervention used as an adjunct to diet and other medications for disease-associated complications in patients with congenital or acquired LD.



## RESULTS

Over the 3-year period, the cumulative budget impact for GL patients was USD 25,297,375, and for PL patients, it was USD 12,276,945. The total costs for Metreleptin strengths (3mg, 5.8mg, and 11.3mg) were USD 2,218,702, USD 11,546,121, and USD 23,809,497, respectively, for the included patient population. After performing scenario analyses, the total budget impact decreased by 20.42% of the overall estimated Metreleptin cumulative budget. The OWSA indicated that the analysis is sensitive to the price of Metreleptin and disease prevalence.

Figure 1: Budget Impact of Metreleptin Different Doses in Lipodystrophy Patients in Saudi Arabia



## OBJECTIVE

The aim of this study is to estimate the budgetary impact of using Metreleptin on payers financial resources to inform decision-making in Saudi Arabia.



## METHODS

A dynamic prevalence-based budget impact analysis was conducted from the perspective of public payers to assess the budget impact of Metreleptin versus standard of care for patients with LD, considering a 3-year time horizon and focusing on Metreleptin different strengths (11.3mg, 5.8mg, and 3mg). In this dynamic model, calculations were based on the following plausible assumptions:

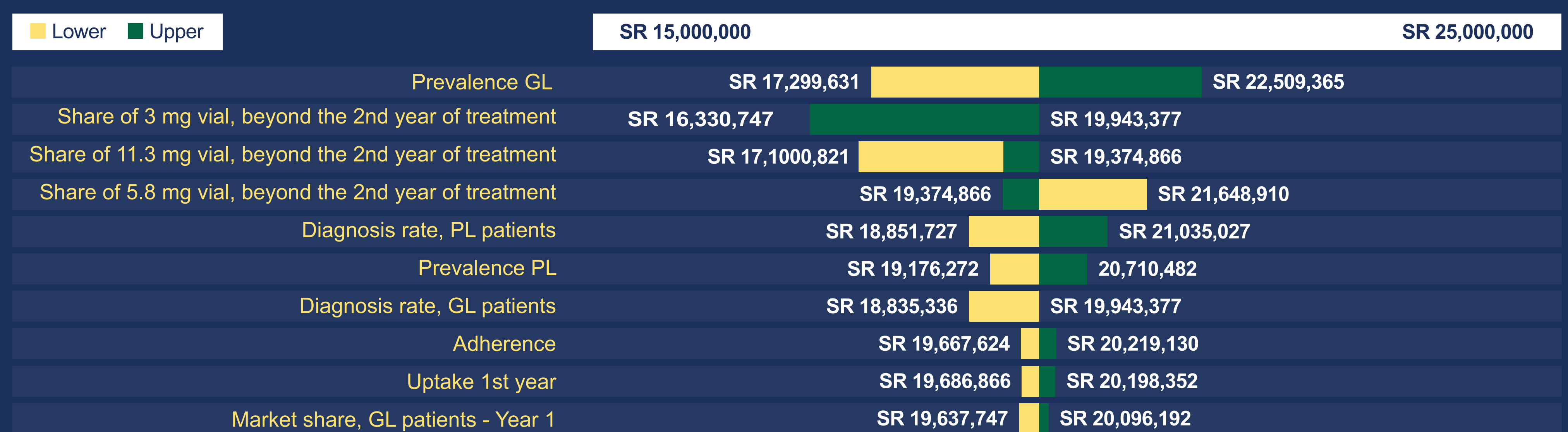
### plausible assumptions

- Total number of treated patients over 3 years = 27 (GL=18, PL=9).
- Patients will remain stable on their doses with corresponding specific vial.
- One year equals 365 days of treatment and patients use 1 vial per day.

- All patients will remain on treatment, although physicians may stop treatment due to inadequate response or side effects.
- No treated patient will die during treatment.
- 0% off-label use for Metreleptin.
- Procurement prices were used for calculating medications costs.
- Market share assumptions were set at 50% in year 1, 75% in year 2, and 100% in year.

The analysis utilized direct medical costs including visits, laboratory tests, investigations, and treatment cost based on LD complications, and LD-eligible patients were identified based on expert input from local physicians who are experts in treating LD patients in Saudi Arabia. To assess the robustness of the results, one-way sensitivity analyses (OWSA) were performed on assumptions covering inputs from the lower to the upper extremes. All OWSA on cost inputs were arranged in a tornado diagram to facilitate analysis. Probabilities in the model were analyzed in a separate tornado diagram but with inputs varied by ±20% given that these were derived from published evidence and key opinion leaders.

Figure 2: Cumulative Budget Impact of Metrelptin Over 3 Years Period



"Prices were converted from SR to USD with a conversion rate of 1 USD = 3.75 SAR"



## CONCLUSIONS

Given the uncertain assumptions regarding the total number of eligible patients for Metreleptin therapy and their subgroups (GL and PL) each year, small variations in patient numbers could have a significant effect on the overall budget impact. Considering medical necessity, risk-sharing strategies such as managed entry agreements are needed to help payers in mitigating such a risk. Moreover, developing a national disease program will help in the early detection and diagnosis of the disease by implementing screening programs. Also, these programs will help the budget holder to allocate the required financial resources efficiently to areas of high priorities.

### References

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### Contact Information

Dr. Hussain Al-Omar

Scan me



### Contact Information

Dr. Fatimah Alyami

Scan me

