

Worth Their Weight?

An Overview of the Initial Reimbursement Decisions for GLP-1 agonists in the EU5

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INTRODUCTION

- Since their regulatory approval, GLP-1 agonists have seen a surge in popularity, with the class expected to dethrone PD-1 inhibitors as the global best-selling drug class in 2024
 - This rapid growth has fuelled a robust pipeline of future weight loss drugs and is shaking up the industry
 - However, US market success may not equally translate to Europe where the payer/HTA hurdle can be significantly greater
- This research aims to evaluate the reimbursement outcomes of current EMA-approved GLP-1 agonists in EU4+UK

METHODS

- Publicly available information was screened to identify EMA-approved GLP-1 agonists with a weight loss indication and identify the corresponding reimbursement outcomes in EU4+UK between January 2015 and June 2024, with key information extracted

RESULTS

- A total of 3 drugs have received EMA approval for weight loss as of June 2024 (semaglutide, liraglutide, tirzepatide) (Table 1)
 - 3/5 countries have granted reimbursement to semaglutide (France: SMR important, ASMR V; Spain: IPT-recommended; UK: optimised to weight-related comorbidities with 2-year stopping rule), while liraglutide is only reimbursed in 1/5 countries (UK: optimised to BMI) as it has not been HTA-assessed in the remaining countries
 - Tirzepatide has yet to be reviewed by HTA agencies in EU4+UK
 - In Germany, all GLP-1s have been excluded from statutory health insurance coverage, with the G-BA citing a legal resolution from 2004 for its decision
 - Similarly, in Italy, all three GLP-1s are classified as Class-C and are not reimbursed

Table 1: Overview of public reimbursement decisions for GLP-1 drugs in EU4+UK (as of June 2024)

GLP-1 drug					
Liraglutide (EMA approval: 03/2015)	Not reimbursed	Not reimbursed	Class-C Not reimbursed	Not reimbursed	Recommended <i>Optimised</i>
Semaglutide (EMA approval: 01/2022)	SMR important; ASMR V <i>Optimised</i>	Not reimbursed	Class-C Not reimbursed	IPT-recommended (SNS negotiation)	Recommended <i>Optimised</i>
Tirzepatide (EMA approval: 11/2023)	In progress	Not reimbursed	Class-C Not reimbursed	Not reviewed	In progress

CONCLUSIONS

- The reception of GLP-1s by European payers has been lukewarm so far. Efficacy concerns in broader populations and legal frameworks pose significant barriers for positive reimbursement in line with their EMA label indication so far in EU4+UK markets
- This may shift, however, in the near future as the competitive landscape evolves with more GLP-1s entering the space

Abbreviations: EMA: European Medicines Agency; SMR: Clinical Value Score; ASMR: Added Clinical Value Score; HTA: Health Technology Assessment; G-BA: Federal Joint Committee

