

SYNOPSIS

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in

Healthcare Analytics

by

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Under the Supervision and Guidance of

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Synopsis

Title of the Research:

GLP-1 and SGLT2 Landscape – Approvals, Evidence, and Market Positioning Insights

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Abstract:

This study aims to analyze the evolving treatment landscape of Type 2 Diabetes Mellitus (T2DM), focusing on GLP-1 receptor agonists and SGLT2 inhibitors. It evaluates regulatory approvals across FDA and EMA, clinical and economic evidence, and payer perceptions influencing market positioning. The research integrates insights from targeted literature reviews (TLR), health technology assessment (HTA) reports, and regulatory datasets to assess comparative effectiveness and cost-efficiency. The findings highlight key differences between these therapy classes and identify factors influencing reimbursement decisions and clinical adoption. The study provides actionable insights to support evidence-based decision-making in pharmaceutical market access and healthcare policy.

Introduction:

The global burden of Type 2 Diabetes Mellitus (T2DM) continues to rise, placing significant pressure on healthcare systems worldwide. Newer antidiabetic therapies, particularly GLP-1 receptor agonists and SGLT2 inhibitors, have transformed disease management by offering benefits beyond glycemic control, including cardiovascular and renal protection.

However, increasing competition among therapies especially semaglutide and tirzepatide has created complexity in clinical decision-making and payer evaluations. While GLP-1 therapies emphasize glycemic control and weight reduction, SGLT2 inhibitors demonstrate strong real-world evidence supporting long-term outcomes.

This research explores how differences in clinical evidence, economic modeling, and regulatory approvals influence the positioning and adoption of these therapies globally.

Literature Review:

Existing literature highlights that GLP-1 receptor agonists, including semaglutide and liraglutide, show superior efficacy in reducing HbA1c levels and body weight. However, many studies rely on surrogate endpoints such as glycemic control and weight reduction, which may not fully represent long-term clinical outcomes.

Conversely, SGLT2 inhibitors such as empagliflozin have demonstrated consistent cardiovascular and renal benefits in both clinical trials and real-world studies.

Economic studies indicate mixed results, with some favoring GLP-1 therapies and others supporting SGLT2 inhibitors. Variations in model assumptions, cost inputs, and study design significantly influence these findings.

Despite extensive research, gaps remain in understanding payer decision-making, especially concerning long-term evidence requirements and economic modelling limitations, which this study aims to address.

Objectives/Aims of the Study:

- To analyze the regulatory approval trends and therapeutic evolution of GLP-1 receptor agonists and SGLT2 inhibitors.
- To evaluate and compare clinical effectiveness, economic evidence, and real-world outcomes of these drug classes.
- To examine payer perspectives and HTA decisions influencing market access and reimbursement.
- To identify key challenges and opportunities in positioning these therapies within the T2DM treatment landscape.

Methodology:

- **Research Design:** Descriptive and Analytical Study
- **Data Source:**
 - Regulatory approval datasets (FDA and EMA)
 - IQVIA TLR and HTA Reports
 - Pharmaceutical and market access presentations
- **Data Collection Methods:**
 - Review of secondary data from reports and datasets
 - Comparative evaluation of clinical, economic, and HTA evidence

- Compilation of drug characteristics, indications, and approval timelines
- **Analysis Tools:**
 - Microsoft Excel for data organization and comparison
 - Qualitative analytical review of literature and HTA findings
- **Expected Outcomes:**
 - Identification of key differences between GLP-1 receptor agonists and SGLT2 inhibitors in terms of clinical and economic value.
 - Understanding of factors influencing HTA decisions and reimbursement outcomes.
 - Insights into limitations of current economic models and evidence gaps.
 - Strategic recommendations to improve market positioning and payer acceptance of therapies.
- **Timeline:**
 - **January 2026 – March 2026:** Literature Review and Data Collection
 - **April 2026 – May 2026:** Data Analysis and Interpretation
 - **May 2026 – June 2026:** Report Writing and Final Submission

References:

- IQVIA TLR & HTA Findings Report, 2024
- IQVIA Objection Handler Report, 2024
- IQVIA HTA Extraction Report, 2024
- GLP-1 and SGLT2 Molecules Dataset (FDA & EMA)
- GLP-1 Molecules Compilation Document
- IQVIA T2D Landscape Presentation, 2026

Appendices:

- Tables illustrating GLP-1 and SGLT2 drug approvals and characteristics
- Comparative charts of clinical and economic evidence
- Summary tables of HTA decisions across different countries