The Incretin Revolution: Transforming Metabolic Medicine Review Article

[1]Kola prudvika, [2]Dr. Aparadhapu Sriharshni Rani.

[1]Department of Pharmacy Practice, Malla Reddy Institute of Pharmaceutical Sciences, Survey No, 593 & 594, near Forest Academy, near Kompally, Dulapally, Bhadhoorpally, Secunderabad, Hyderabad, Telangana 500100, India

[2]Department of Pediatrics, Malla reddy Medical College For Women, India

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ABSTRACT

Background: The class of drugs known as glucagon-like peptide-1 receptor agonists (GLP-1 RAs) has significantly changed how type 2 diabetes mellitus (T2DM) and obesity are treated. Since the 1980s, when the role of incretins was first discovered, and up to the recent approval of drugs that combine multiple active ingredients, this development has been one of the most important achievements in modern endocrinology.

Methods: This review provides an overview of key randomized controlled trials, regulatory documents, and new drug development data for both peptide and non-peptide GLP-1 RAs.

It evaluates their effectiveness, impact on cardiovascular health, side effects, and areas where more research is needed.

Results: GLP-1 RAs consistently lower HbA1c levels by 1 to 2 percent, reduce body weight by 5 to 22 percent, and decrease the risk of major cardiovascular events by 9 to 20 percent.

Newer drugs, such as poly-agonists like tirzepatide and retatrutide, and orally available small molecules like orforglipron, are expanding the range of treatment options.

Conclusions: GLP-1 based treatments have the potential to tackle both type 2 diabetes and obesity, but issues like cost, tolerability, and long-term safety continue to pose challenges.

Keywords: GLP-1 receptor agonist; incretin; semaglutide; tirzepatide; obesity; type 2 diabetes; cardiovascular outcomes; non-peptide oral agonist

INTRODUCTION TO GLP-1 RECEPTOR AGONISTS

Historical Background — The Past

The incretin effect, which refers to the increased insulin release seen when glucose is taken by mouth rather than through an intravenous injection, was first described by Elrick et al. in 1964. [1] Later, the hormones responsible for this effect, glucose-dependent insulinotropic polypeptide (GIP) and glucagon-like peptide-1 (GLP-1), were identified. [2] Importantly, the ability of GLP-1 to stimulate insulin production is dependent on glucose levels, which helps avoid the risk of low blood sugar that was a problem with earlier drugs that promoted insulin release. [3]

A chance discovery revealed that exendin-4, a peptide found in the saliva of the Gila monster lizard (Heloderma suspectum), had about 53% similarity to human GLP-1 and was not broken down by the enzyme dipeptidyl peptidase-4 (DPP-4), which led to the development of new drugs.

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[4] Exenatide, a synthetic version of exendin-4, was approved by the FDA in 2005 as the first GLP-1 receptor agonist, marking a significant moment in the study of incretin-based treatments. [3,4]

Initially, early GLP-1 receptor agonists like exenatide (taken twice daily) and liraglutide (taken once daily) were short-acting peptides that could cause immune reactions and needed daily injections, which limited their use.

[5,6] However, the development of longer-acting formulations, such as exenatide extended-release, albiglutide, and dulaglutide, which are taken once a week, greatly improved patient compliance. [11,12]

Current Agents — The Present

The key breakthrough came with the development of fatty-acid-linked versions of GLP-1 analogues. Liraglutide, which is modified with a C-16 acylated fatty acid, allows for once-daily administration due to its binding to albumin. It showed beneficial effects on the heart in the LEADER study, with a hazard ratio of 0.87 (95% confidence interval 0.78–0.97), and led to weight loss of up to 8% in the SCALE trials. [5,6]

Semaglutide is currently the most advanced form of GLP-1 monotherapy.

It uses a C-18 fatty di-acid linker, which significantly increases its duration of action to about seven days, allowing for once-weekly subcutaneous injections (Ozempic, 0.5–2 mg). This results in a reduction of HbA1c levels by approximately 1.5–1.8% and weight loss of about 5–9%. [7] The SUSTAIN-6 trial confirmed that semaglutide also reduces cardiovascular risk, with a hazard ratio of 0.74. [8] Notably, the SALSA technology made it possible to develop oral semaglutide (Rybelsus, 3–14 mg), the first orally available peptide-based GLP-1 receptor agonist, by using absorption enhancers that temporarily improve the permeability of the stomach lining. [9]

Higher doses of semaglutide, such as 2.4 mg (Wegovy), marked a new era in the treatment of obesity.

The STEP-1 trial showed a mean weight loss of 14.9% compared to 2.4% with a placebo, which is greater than the effects of all previously available anti-obesity medications. [10] The SELECT study (2023) further demonstrated a 20% reduction in major adverse cardiovascular events (MACE) in individuals who were overweight or obese but did not have diabetes, reinforcing the role of GLP-1 receptor agonists as drugs that affect both cardiovascular and metabolic health. [8]

Tirzepatide (Mounjaro/Zepbound), a dual agonist of both GIP and GLP-1 receptors, was approved in 2022–2023.

It achieved up to 22.5% weight loss in the SURMOUNT-1 trial, surpassing the effects of semaglutide at 2.4 mg in direct comparisons. In the SURPASS trials, it also reduced HbA1c levels by approximately 2.1%. [15,16]

Pipeline & Future Agents

Triple-agonism is the cutting-edge area of research. Retatrutide, a drug that acts as a triple agonist for GIP, GLP-1, and glucagon, developed by Eli Lilly, resulted in up to 24.2% weight loss in Phase II trials over 48 weeks — this is the highest weight loss recorded from any medication. [17] CagriSema, which is an amylin analogue combined with semaglutide at 2.4 mg, showed approximately 22.7% weight reduction in Phase II CO-DEVELOP trials. [18]

Non-peptide oral small-molecule GLP-1 receptor agonists are a significant breakthrough to meet unmet medical needs.

Orforglipron, a non-peptide, once-daily oral GLP-1 RA developed by Eli Lilly, does not require fasting, and in Phase II trials, it led to 14.7% weight loss and about 2% decrease in HbA1c levels. It is currently undergoing

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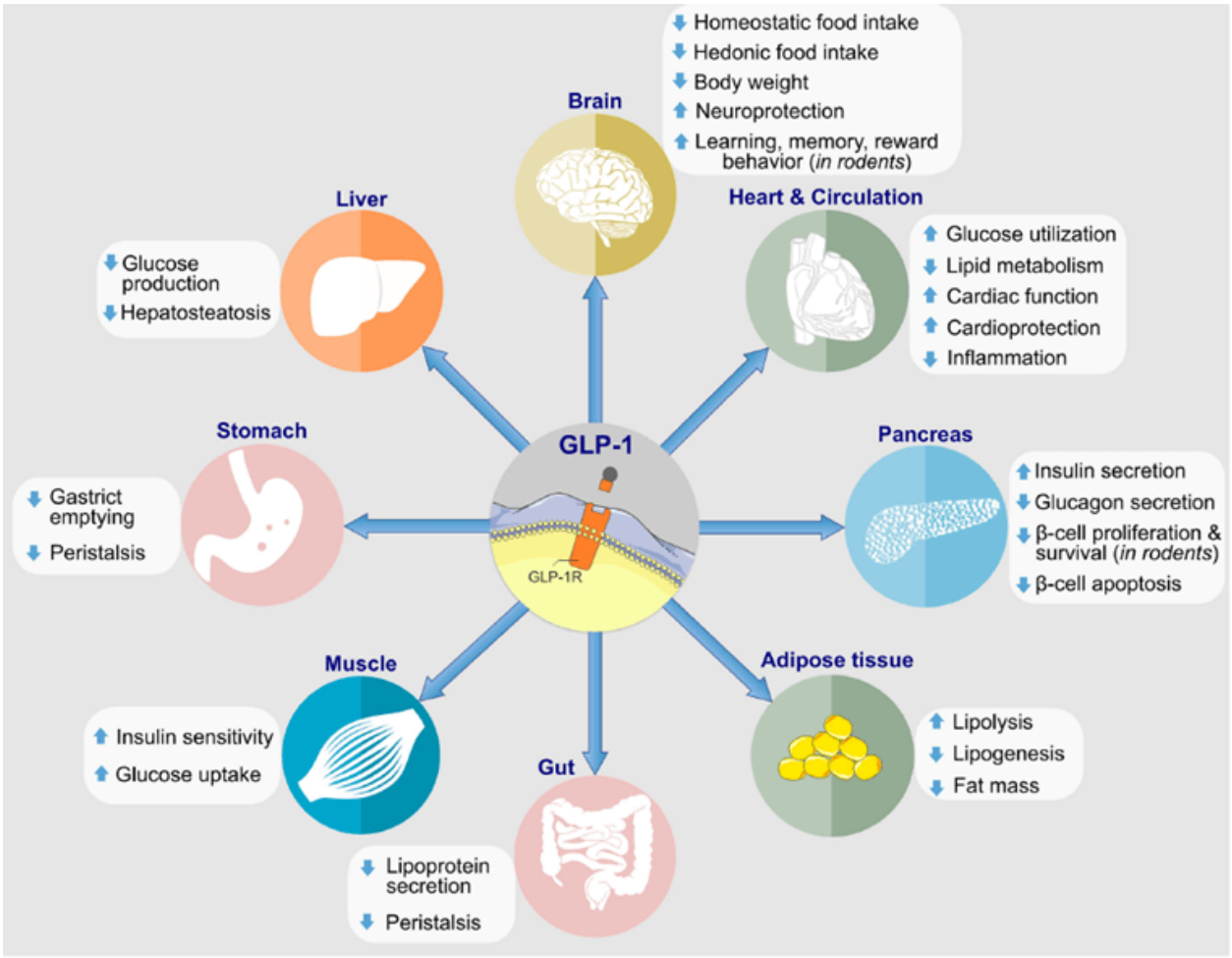
large Phase III trials. [19] Danuglipron, from Pfizer, achieved approximately 11% weight loss in Phase II trials. [20] These medicines have the potential to improve access to treatment in low-resource areas.

Other promising developments include formulations targeted to specific organs, such as inhaled GLP-1 RAs for the lungs.

There are also analogues designed to affect the central nervous system for conditions like neurodegeneration, including trials for Alzheimer's and Parkinson's disease. Combination devices, such as fixed-dose oral combinations of GLP-1 RAs and SGLT2 inhibitors, are also being explored. Additionally, personalized prescribing based on genetic variations in the GLP-1 receptor is being studied. [22,23]



Summary of Key Glp-1 Receptor Agonists: Peptide & Non-Peptide

Table 1 provides a structured comparison of approved and late-stage investigational GLP-1 RAs, categorised by molecular class, dosing, route, frequency, and principal adverse effects. ‡ = withdrawn from market.

Drug (Brand)	Class	Dose	Route	Frequency	Key Side Effects	Ref
Exenatide (Byetta)	Peptide	5–10 mcg	SC injection	Twice daily	N/V/D, hypoglycaemia, pancreatitis risk	[3,4]
Exenatide ER (Bydureon)	Peptide	2 mg	SC injection	Once weekly	Injection-site nodules, N/V, pancreatitis risk	[3,4]
Liraglutide (Victoza/Saxenda)	Peptide	0.6–1.8 mg (T2DM); 3 mg	SC injection	Once daily	N/V/D, tachycardia, pancreatitis, MTC risk	[5,6]

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		(obesity)				
Semaglutide SC (Ozempic)	Peptide	0.25–2 mg	SC injection	Once weekly	N/V/D, gastroparesis, pancreatitis	[7,8]
Semaglutide oral (Rybelsus)	Peptide (oral)	3–14 mg	Oral tablet	Once daily (fasting)	N/V/D, dyspepsia, eructation	[7,9]
Semaglutide 2.4 mg (Wegovy)	Peptide	0.25→2.4 mg	SC injection	Once weekly	N/V/D, constipation, fatigue	[8,10]
Dulaglutide (Trulicity)	Peptide	0.75–4.5 mg	SC injection	Once weekly	N/V/D, abdominal pain, HR increase	[11]
Albiglutide (Tanzeum) ‡	Peptide	30–50 mg	SC injection	Once weekly	Upper respiratory infection, N/V (discontinued)	[12]
Lixisenatide (Adlyxin)	Peptide	10–20 mcg	SC injection	Once daily	N/V, headache, hypoglycaemia	[13]
Efpeglenatide	Peptide	4–6 mg	SC injection	Once weekly	N/V/D (Phase III)	[14]
Tirzepatide (Mounjaro/Zepbound)	Peptide (GIP/GLP-1)	2.5–15 mg	SC injection	Once weekly	N/V/D, decreased appetite, pancreatitis	[15,16]
Retatrutide	Peptide (GIP/GLP-1/Gcg)	4–12 mg	SC injection	Once weekly (Phase III)	N/V/D, tachycardia	[17]
Cagrilintide+Sema (CagriSema)	Peptide combo	2.4+2.4 mg	SC injection	Once weekly (Phase III)	N/V/D, injection-site reactions	[18]
Orforglipron	Non-peptide oral	12–45 mg	Oral tablet	Once daily (Phase III)	N/V/D, dyspepsia	[19]
Danuglipron	Non-peptide oral	TBD	Oral tablet	Once daily (Phase II)	N/V, headache	[20]
LY3502970 (Orfoglipron analogue)	Non-peptide oral	TBD	Oral tablet	Once daily (Phase II)	GI effects	[21]

N/V/D = nausea, vomiting, diarrhoea. SC = subcutaneous. MTC = medullary thyroid carcinoma. HR = heart rate. T2DM = type 2 diabetes mellitus.

EXAMINATION OF EVIDENCE BASE: SUPPORT, STRENGTHS & WEAKNESSES

Author/Researcher Support for GLP-1 RAs

The body of evidence supporting the superiority of GLP-1 receptor agonists over older glucose-lowering medications is strong and well-supported across multiple areas. Drucker and Nauck, who were key researchers in this field, helped establish the biological understanding of GLP-1 and applied it to clinical pharmacology through extensive research over more than three decades. [2,3] Following regulations set by the FDA after 2008, industry-funded cardiovascular outcomes trials provided large-scale, definitive results: studies such as LEADER, SUSTAIN-6, HARMONY, AMPLITUDE-O, and SURPASS-CVOT all showed either neutral or better outcomes regarding major adverse cardiovascular events. [5–8,11,14]

Independent meta-analyses, including those by Zelniker et al. (Lancet 2019) and Sattar et al. (Lancet 2021), confirmed the cardiovascular and kidney benefits of GLP-1 receptor agonists.

Additionally, studies on the underlying mechanisms have demonstrated additional benefits beyond blood sugar control, such as reducing atherosclerosis, inflammation, and regulating appetite. [22,23]

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Strengths of the Evidence

1.Cardiovascular Evidence: There are several large cardiovascular outcome trials (CVOTs), each involving more than 3,000 to 17,000 participants, with outcomes measured using hard endpoints such as major adverse cardiovascular events (MACE), hospitalisations for heart failure, and renal outcomes. [5–8]

2.Obesity Pharmacotherapy: The STEP and SURMOUNT programmes used double-blind, placebo-controlled randomised controlled trial designs with follow-up periods lasting 68 to 104 weeks. These trials demonstrated long-lasting weight loss benefits that are rare in pharmacological treatments. [10,15]

3.Mechanistic Breadth: Both preclinical and clinical data show that the treatment has anti-steatotic effects, as seen in the SYNERGY-NASH study, where non-alcoholic fatty liver disease (MASH) was resolved. It also provides cardioprotection through direct activation of GLP-1 receptors in the heart, renoprotection as shown in the FLOW trial—where semaglutide reduced the progression of kidney failure by 24%—and emerging signs of neuroprotection. [22,23]

4.Real-World Data: Observational studies such as HARMONY and US claims databases have confirmed the findings from clinical trials in a wide range of patients with multiple health conditions, thereby improving the generalisability of the results. [12]

Weaknesses & Limitations

1.Tolerability: Gastrointestinal side effects, such as nausea (20–44%), vomiting (8–24%), and diarrhoea (8–30%), are the main reasons for stopping treatment, especially during the initial dose increase. There is also a risk of gastroparesis, which is not well understood and may require special care during anaesthesia. [3–10]

2.Pancreatitis Signal: There is a biologically plausible but controversial link between the treatment and acute pancreatitis and pancreatic ductal adenocarcinoma. This association requires ongoing monitoring. The FDA has included a warning in the drug label. [3,5]

3.Medullary Thyroid Carcinoma: Some rodent studies have shown C-cell hyperplasia, which has led to a general contraindication for patients with a personal or family history of multiple endocrine neoplasia type 2 (MEN-2) or medullary thyroid cancer (MTC), even though there are no confirmed cases in humans. [5,6]

4.Cost and Access: In the USA, the annual cost of these drugs, such as semaglutide and tirzepatide, ranges from USD 10,000 to USD 15,000, creating significant inequity. Low- and middle-income countries, which have the highest burden of type 2 diabetes, often have very limited access to these medications. The development of biosimilar versions is still in its early stages. [23]

5. Long-Term Safety Unknown: None of the major trials have followed patients for more than five years. The long-term impact on bone density, muscle mass (which can decrease along with fat loss), gallbladder disease (with a 1.3-fold increased risk of gallstones), and cancer risk remains unclear. [10,15]

6. Trial Homogeneity: Most of the major trials included predominantly White, middle-aged, high-income participants. There is limited research on how different ethnic groups, due to variations in pharmacogenomics, might respond to the drug due to differences in GLP-1 receptor expression. [22]

Editorial Viewpoint & Supporting Argument

The author argues that GLP-1 receptor agonists are the most significant drug class in metabolic medicine since metformin was introduced — and may even offer greater benefits. This argument is based on four key points:

First, broad and varied effectiveness: no previous medication has successfully lowered HbA1c, reduced body weight, decreased systolic blood pressure, lowered triglycerides, reduced cardiovascular events, and slowed kidney disease progression all at the same time, as shown in major clinical trials.

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The SELECT trial showed that semaglutide can reduce major adverse cardiovascular events by 20% in non-diabetic obese people, which changes how this drug class is viewed from just a treatment for diabetes to a modifier of cardio-metabolic diseases. [8,10]

Second, the promise of its mechanism: GLP-1 receptors are present in the heart, kidneys, liver, lungs, digestive system, and brain.

The high rates of metabolic-associated steatotic hepatitis (MASH) resolution seen with semaglutide (~40% histological improvement, ESSENCE trial 2024) and hints of a potential role in Alzheimer's disease (EVOKE trial) indicate that this drug class still has much therapeutic potential. [22,23]

Third, a change in how obesity is understood: obesity has traditionally been viewed as a lifestyle issue rather than a neurobiological condition.

The strong appetite-suppressing effects of GLP-1 receptor agonists on the brain support the use of medication for obesity treatment, which could help prevent related conditions like type 2 diabetes, high blood pressure, sleep apnea, and cancer on a larger scale. [10,15–17]

Fourth, the development of an oral, non-peptide medication: orforglipron entering Phase III trials marks a major advance by eliminating the need for injections and refrigeration, making GLP-1 RA treatment more accessible in primary care and resource-limited areas. [19] However, this optimism should be balanced.

For this drug class to achieve its full potential, healthcare systems must invest in fair access, structured prescribing guidelines, and systems to monitor for rare long-term side effects. The fact that most people regain nearly all the weight lost after stopping the medication — within one year — highlights the chronic nature of obesity and the need for either long-term treatment or additional lifestyle or surgical options. [10,23]

Analysis of the Incretin Revolution: Implications

Clinical Practice Implications

Current guidelines for diabetes management (ADA 2024, EASD 2023) recommend GLP-1 RAs as the preferred add-on treatment for patients with type 2 diabetes who have existing or high risk of cardiovascular disease, heart failure (including both HFpEF and HFrEF), chronic kidney disease, or obesity, regardless of their HbA1c levels.

[22] This change in approach, moving away from a focus on glucose control to one that includes cardiovascular, renal, and weight management, requires healthcare providers to be re-educated and to use shared decision-making processes that consider factors like the ease of injection, cost, and how to manage side effects. [23]

Health Economics & Policy

Studies that model the use of GLP-1 RAs suggest that widespread adoption could prevent about 500,000 cardiovascular events and save between USD 1.0 and 1.5 trillion in US healthcare costs over a period of ten years.

[22] However, the current pricing structure, shaped by patent monopolies in the production of biological drugs, benefits mainly insured individuals from high-income groups. Necessary policy actions include requiring value-based pricing discussions, fast-tracking the approval of biosimilars (as outlined in the FDA's 2023 guidance for new biologics), and adopting public health procurement strategies similar to those used for insulin. [23]

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Societal & Ethical Implications

The increasing focus on obesity as a medical condition raises important ethical concerns about personal autonomy, what counts as a disease, and the potential for creating pharmaceutical dependence instead of stigma.

As GLP-1 RAs start being used in the weight-loss market for non-obese, non-diabetic individuals, there is a risk of shortages that affect patients who need these drugs for medical reasons, as seen with the semaglutide shortages between 2022 and 2024. [22,23] Regulatory systems must clearly separate the use of these drugs for therapeutic purposes from their use for lifestyle or cosmetic weight loss. [22]

Translational Implications

The development of GLP-1 RAs shows the effectiveness of combining comparative genomics (such as the use of exendin-4 from the Gila monster), structural biology (like extending drug half-life through fatty-acid conjugation), and regulatory science driven by cardiovascular outcome trials (CVOTs).

The story of GLP-1 RAs should serve as a model for speeding up the development of other under-researched metabolic targets, such as GLP-2 for intestinal recovery, FGF-21 analogues for non-alcoholic fatty liver disease (MASH), amylin analogues for combination obesity therapy, and GIP receptor agonists for neurodegenerative diseases. [17,18,22]

SUMMARY, EVALUATION & PROPOSED FUTURE RESEARCH

Summary

The GLP-1 receptor agonist (GLP-1 RA) class has developed over four decades from a simple endocrinological finding to a major therapeutic breakthrough worth billions of dollars.

Important developments include: the identification of GLP-1 in 1983, the discovery of exendin-4 in 1992, the FDA approval of exenatide in 2005, the cardiovascular benefits of liraglutide shown in the LEADER trial in 2016, the approval of semaglutide for obesity in the STEP-1 trial in 2021, the approval of tirzepatide as a dual-agonist in 2022, the cardiovascular benefits of SELECT in obesity without diabetes in 2023, and the upcoming availability of oral, non-peptide GLP-1 RAs. [1–21]

Evaluation

The overall evidence for GLP-1 RAs is considered high quality according to GRADE criteria.

This is based on multiple large, blinded randomised controlled trials (RCTs) with clear clinical outcomes, consistent biological plausibility, and validation through real-world data. However, some uncertainties remain, including (a) the long-term safety beyond five years, (b) the best duration of treatment and procedures for re-treatment after stopping, (c) the effectiveness of combination therapies, and (d) the applicability across different ethnic groups. [22,23]

Proposed Future Research Priorities

Priority 1 — Long-Term Safety Monitoring: Ten-year open-label follow-up studies of semaglutide and tirzepatide to assess bone density, lean body mass, biliary disease, and cancer rates. [22]

Priority 2 — Optimal Therapy Duration and Discontinuation: RCTs comparing continuous versus intermittent GLP-1 RA use, combined with lifestyle interventions, to identify the minimum effective treatment duration. [10,23]

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Priority 3 — Combination Pharmacology: Head-to-head trials comparing GLP-1 RA plus SGLT2 inhibitor versus triple-agonist monotherapy; trials assessing combination with bariatric surgery versus drug-only treatment. [22]

Priority 4 — Underserved Populations: Special RCTs in South and East Asian, Sub-Saharan African, and Latin American populations, with tailored dose-finding pharmacokinetic studies due to differences in body composition and GLP-1 receptor polymorphisms. [22,23]

Priority 5 — CNS and MASH Conditions: Completion of EVOKE (Alzheimer's), ESSENCE (MASH), and PARKINSON'S-LIRA trials to explore new therapeutic uses. [22]

Priority 6 — Non-Peptide Oral Molecules: Phase IV monitoring of orforglipron and danuglipron after market approval, including cardiovascular outcomes, drug interactions, and real-world adherence. [19,20]

Priority 7 — Health Technology Assessment and Access: Cost-effectiveness models in low- and middle-income countries (LMICs); assessment of the impact of generic or biosimilar GLP-1 RAs on the global burden of type 2 diabetes mellitus (T2DM) and obesity. [23]

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