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Health Technology Briefing
July 2025

Retatrutide for managing overweight or obesity

Company/Developer	Eli Lilly and Company Ltd

☒ New Active Substance ☐ Significant Licence Extension (SLE)

NIHRIO ID: 37610	NICE ID: Not Available	UKPS ID: 674950

Licensing and Market Availability Plans

Currently in phase III clinical development.

Summary

Retatrutide is in clinical development for the treatment of patients with overweight or obesity. Overweight and obesity are typically defined by a body mass index (BMI) over 25 and 30, respectively. While this is commonly caused by excessive calorie intake, overweight and obesity are complex conditions with many other potential multifactorial causes. In the UK, about 1 in 4 adults are living with obesity, leading to serious health conditions and a life expectancy reduced by three to ten years. For many people, lifestyle and behavioural changes alone may not help. Existing medicines for weight loss use either a singular or dual approach. They either work by reducing the breakdown of fats or by activating hormones called glucagon-like peptide 1 (GLP-1) and glucose-dependent insulinotropic polypeptide (GIP), which promote weight loss.

Retatrutide mimics the effects of naturally occurring gut hormones by acting as a triple receptor agonist, meaning it activates three key hormone pathways that play a role in glucose metabolism and appetite regulation. In the phase III trials, retatrutide is given by subcutaneous injection (injection under the skin). If licensed retatrutide will provide an additional treatment option for patients with obesity or overweight.

Proposed Indication

This briefing reflects the evidence available at the time of writing and a limited literature search. It is not intended to be a definitive statement on the safety, efficacy or effectiveness of the health technology covered and should not be used for commercial purposes or commissioning without additional information. A version of the briefing was sent to the company for a factual accuracy check. The company was available to comment.

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Retatrutide is proposed for use in patients with overweight or obesity.[a]

Technology

Description

Retatrutide (LY3437943) is single peptide conjugated to a fatty diacid moiety that is an agonist of the glucose-dependent insulinotropic polypeptide receptor (GIPR), glucagon-like peptide 1 receptor (GLP-1R), and glucagon (GCG) receptors.[1,2] GLP-1 and GCG are known to significantly delay gastric emptying in humans, therefore retatrutide exerts these effects through agonism of their receptors.[3,4] Delayed gastric emptying slows the release and movement of food from the stomach to the intestines which reduces food consumption and therefore leads to weight reduction.[4] GIP does not have any effect on gastric emptying but it triggers the beta cells in the pancreas to produce insulin, which leads to an increase in insulin levels in the blood. The GLP-1 hormone works in a similar way to GIP and also causes an increase in blood insulin levels. The increased insulin levels lower blood sugar levels which can also help people lose weight.[5]

Retatrutide is in clinical development for the management of adult patients with obesity and overweight. In the phase III clinical trials TRIUMPH-1 (NCT05929066), TRIUMPH-2 (NCT05929079), TRIUMPH-3 (NCT05882045), TRIUMPH-4 (NCT05931367), retatrutide was given subcutaneously (SC) at defined doses for 80 weeks in TRIUMPH-1, TRIUMPH-2, and TRIUMPH-3 and 68 weeks in TRIUMPH-4.[6-9] The phase II study involved retatrutide 1 mg, 4 mg (with initial dose of 2 mg), 4 mg (with initial dose of 4 mg), 8 mg (with initial dose of 2 mg), 8 mg (with initial dose of 4 mg), 12 mg (with initial dose of 2 mg) or placebo, administered subcutaneously once weekly for 48 weeks. [10,11]

Key Innovation

With an increasing prevalence of obesity, there is an unmet need for novel approaches to improve weight management. Currently approved technologies for people with overweight or obesity are either lipase inhibitors, GLP-1R agonists or both GLP-1R and GIPR agonists.[12-14] The pharmacokinetics of retatrutide are considered dose-proportional; it has a half-life of approximately 6 days, which enables weekly administration.[1] Multi-receptor agonists such as retatrutide may provide additional advantages over currently approved therapies, given its triple agonist activity at the glucagon, GIP, and GLP-1 receptors.[15,16]If licensed, retatrutide will offer an additional treatment option for adult patients living with obesity or that are overweight.

Regulatory & Development Status

Retatrutide does not currently have Marketing Authorisation in the EU/UK for any indication.

Retatrutide is currently in clinical development for the following indications:[17]

- Type 2 diabetes
- Atherosclerotic cardiovascular disease
- Chronic kidney disease
- Cardiovascular diseases
- Obstructive sleep apnoea

Patient Group

Disease Area and Clinical Need

[a] Information provided by Eli Lilly and Company Ltd

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Overweight and obesity are defined as abnormal or excessive fat accumulation that presents a risk to health. For most adults a body mass index (BMI) over 25 is considered overweight, and over 30 is obese although for those with Asian, Chinese, Middle Eastern, Black African or African-Caribbean family background a lower BMI score is used (23-27.4 is considered overweight and 27.5 or above is considered obese).[18,19] Obesity and overweight are caused when extra calories, particularly those from foods high in fat and sugar, are stored in the body as fat. In most cases obesity is a multifactorial disease due to obesogenic environments, psycho-social factors and genetic variants.[20] The role of genetic predisposition to obesity has been widely demonstrated, with the approximate heritability of obesity ranging from 40–70%.[21] Living with obesity can cause a number of further problems, including difficulties with daily activities and health conditions including tiredness, joint and back pain and low confidence as well as more serious health conditions such as type 2 diabetes, osteoarthritis, sleep apnoea, hypertension, and heart disease.[18,21]

In the UK, it is estimated that around 1 in every 4 adults are living with obesity, and the disease can reduce life expectancy by an average of 3 to 10 years, depending on how severe it is.[18] In England (2023-24), there were 11,221 finished consultant episodes (FCE) and 9,763 admissions for obesity (ICD-10 code E66) which resulted in 25,123 FCE bed days and 2,457 day cases.[22]

Recommended Treatment Options

The National Institute for Health and Care Excellence (NICE) recommends prevention and lifestyle weight management services for adults who are becoming overweight or obese.[23] Drug treatment should only be considered once dietary and physical activity interventions have been started and evaluated, or as part of an integrated approach to weight management.[24]

NICE recommends the following treatment options for managing a person who is living with overweight or obesity:

- Orlistat[21b]
- Liraglutide[25]
- Semaglutide[26]
- Trizepatide[27]

Clinical Trial Information

Trial	**TRIUMPH-1**, NCT05929066; A master protocol to investigate the efficacy and safety of LY3437943 once weekly in participants without type 2 diabetes who have obesity or overweight: A randomized, double-blind, placebo-controlled trial (TRIUMPH-1) **Phase III** – Active, not recruiting **Locations:** 4 EU countries, UK, USA, Canada and other countries **Primary completion date**: April 2026
Trial Design	Randomised, parallel assignment, double-blind
Population	N=2300 (estimated); participants with a BMI ≥30.0 kilograms per square meter (kg/m^2), or ≥27.0 kg/m^2 with at least one of the following: hypertension, dyslipidaemia, obstructive sleep apnoea, or cardiovascular disease; adults aged 18 years and older.

[b] There is no NICE technology appraisal guidance on orlistat

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Intervention(s)	Retatrutide administered subcutaneously
Comparator(s)	Placebo administered subcutaneously
Outcome(s)	Primary outcome measures: • Percent change from baseline in body weight [time frame: baseline, week 80] • Change from baseline in the western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) pain subscale score for GOA1 subset [time frame: baseline, week 80] • Change from baseline in Apnea-Hypopnea Index (AHI) events per hour for GSA1 Subset [time frame: baseline, week 80] See trial record for full list of other outcomes.
Results (efficacy)	-
Results (safety)	-

Trial	**TRIUMPH-4**, NCT05931367; A Phase 3 Study to Investigate the Efficacy and Safety of LY3437943 Once Weekly in Participants Who Have Obesity or Overweight and Osteoarthritis of the Knee: A Randomised, Double-Blind, Placebo-Controlled Trial **Phase III** – Active, not recruiting **Locations:** One EU country, UK, USA, Canada and other countries **Primary completion date**: December 2025
Trial Design	Randomised, parallel assignment, double-blind
Population	N=405 (estimated); participants with a BMI ≥27 kilogram/kg/m² at screening, a history of at least one self-reported unsuccessful dietary effort to lose body weight; adults aged 18 years and older.
Intervention(s)	Retatrutide administered subcutaneously
Comparator(s)	Placebo administered subcutaneously
Outcome(s)	Primary outcome measures: • Change from baseline in the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) pain subscale score [time frame: baseline, week 68] • Percent change from baseline in body weight [time frame: baseline, week 68] See trial record for full list of other outcomes.
Results (efficacy)	-
Results (safety)	-

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Trial	**TRIUMPH-2**, NCT05929079; A master protocol to investigate the efficacy and safety of LY3437943 once weekly in participants with type 2 diabetes mellitus who have obesity or overweight: A randomised double-blind, placebo-controlled trial **Phase III** – Active, not recruiting **Locations:** 2 EU countries, USA and other countries **Primary completion date**: May 2026
Trial Design	Randomised, parallel assignment, double-blind
Population	N=1000 (estimated); participants with a BMI greater than or equal to 27.0 kilogram/square meter (kg/m ^{2}), type 2 diabetes on stable treatment and have a history of at least one unsuccessful dietary effort to lose body weight; adults aged 18 years and older.
Intervention(s)	Retatrutide administered subcutaneously
Comparator(s)	Placebo administered subcutaneously
Outcome(s)	Primary outcome measures: • Percent change from baseline in body weight [time frame: baseline, week 80] • Change from baseline in Apnea-Hypopnea Index (AHI) for GSA2 subset [time frame: baseline, week 80] See trial record for full list of other outcomes.
Results (efficacy)	-
Results (safety)	-

Trial	**TRIUMPH-3**, NCT05882045; A randomised, double-Blind, phase 3 study to investigate the efficacy and safety of LY3437943 once weekly compared to placebo in participants with severe obesity and established cardiovascular disease **Phase III** – Active, not recruiting **Locations:** 4 EU countries, USA, Canada and other countries **Primary completion date**: January 2026
Trial Design	Randomised, parallel assignment, double-blind.
Population	N=1800 (estimated); participants with a BMI ≥35.0 kilogram/square meter (kg/m^2) with at least one self-reported attempt to reduce weight, established cardiovascular disease with at least one of the following: prior myocardial infarction, prior ischaemic or haemorrhagic stroke, or symptomatic peripheral arterial disease; adults aged 18 years and older
Intervention(s)	Retatrutide administered subcutaneously
Comparator(s)	Placebo administered subcutaneously

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Outcome(s)	Primary outcome measure: • Percent change from baseline in body weight [time frame: baseline, week 80] See trial record for full list of other outcomes.
Results (efficacy)	-
Results (safety)	-

Trial	**TRIUMPH-6**, NCT06859268; A Phase 3b, Randomised, Double-Blind, Placebo-Controlled Study to Evaluate Retatrutide Treatment in the Maintenance of Weight Reduction in Individuals With Obesity **Phase III** – Recruiting **Locations:** USA, Canada and UK **Primary completion date**: April 2028
Trial Design	Randomised, parallel assignment, double-blind
Population	N=586 (estimated); obesity and a history of at least one self-reported unsuccessful dietary effort to reduce body weight; adults aged 18 years and older.
Intervention(s)	Retatrutide administered subcutaneously
Comparator(s)	Placebo administered subcutaneously
Outcome(s)	Primary outcome measures: • Percent change from baseline in body weight [time frame: baseline, week 116] See trial record for full list of other outcomes.
Results (efficacy)	-
Results (safety)	-

Trial	NCT04881760 ; A Phase 2 Study of Once-Weekly LY3437943 Compared With Placebo in Participants Who Have Obesity or Are Overweight With Weight-Related Comorbidities **Phase II** – Completed **Locations:** USA and Puerto Rico **Study completion date**: November 2022
Trial Design	Randomised, parallel assignment, double-blind
Population	N=338 (actual); participants who have obesity or are overweight with weight-related comorbidities; adults aged 18 years to 75 years
Intervention(s)	All participants received retatrutide via SC injection once weekly (QW), with different dosing strategies:

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	• 1 mg retatrutide: fixed dose of 1 mg weekly. • 4 mg retatrutide (2 mg titration): started with 2 mg, then increased to 4 mg weekly. • 4 mg retatrutide: fixed dose of 4 mg weekly. • 8 mg retatrutide (2 mg titration): started with 2 mg, then increased to 4 mg, and then to 8 mg weekly. • 8 mg retatrutide (4 mg titration): started with 4 mg, then increased to 8 mg weekly. • 12 mg retatrutide (2 mg titration): started with 2 mg, then increased sequentially to 4 mg, 8 mg, and finally to 12 mg weekly.
Comparator(s)	Participants received placebo matched to retatrutide administered as SC injection once-weekly (QW).
Outcome(s)	Primary outcome measure: • Mean percent change from baseline in body weight at baseline and week 24. See trial record for full list of other outcomes.
Results (efficacy)	All the participants treated with retatrutide at a dose of 8 mg or 12 mg in this trial had a weight reduction 5% or more. With the 12-mg dose of retatrutide, more than 9 of 10 participants lost 10% or more of their baseline weight, nearly two thirds lost 20% or more, nearly half lost 25% or more, and a quarter lost 30% or more.[28]
Results (safety)	Overall, adverse events during the treatment period were reported in 70% of the participants in the placebo group and in 73 to 94% of the participants in the retatrutide groups, with the highest incidence in the 8-mg and 12-mg groups. Discontinuation of retatrutide or placebo due to adverse events occurred in 6 to 16% of the participants who received retatrutide and in none of the participants who received placebo. Fifteen serious adverse events occurred in 13 participants, with similar frequencies in the retatrutide group and the placebo group.[28]

Estimated Cost

The cost of retatrutide is not yet known.

Relevant Guidance

NICE Guidance

- NICE technology appraisal. Tirzepatide for managing overweight and obesity (TA1026). December 2024.
- NICE technology appraisal. Semaglutide for managing overweight and obesity (TA875). March 2023.
- NICE technology appraisal. Liraglutide for managing overweight and obesity (TA664). December 2020.

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- NICE technology appraisal. Naltrexone–bupropion for managing overweight and obesity (TA494). December 2017.
- NICE clinical guideline. Overweight and obesity management (NG246). January 2025.
- NICE clinical guideline. Obesity: identification, assessment and management (CG189). November 2014.
- NICE quality standard in development. Overweight and obesity management (GID-QS10183). Publication anticipated August 2025.
- NICE quality standard. Obesity: clinical assessment and management (QS127). August 2016.
- NICE quality standard. Obesity in adults: prevention and lifestyle weight management programmes (QS111). January 2016.
- NICE interventional procedures guidance. Endoscopic sleeve gastroplasty for obesity (IPG783). February 2024.
- NICE interventional procedures guidance. Implantation of a duodenal–jejunal bypass sleeve for managing obesity (IPG471). November 2013.

NHS England (Policy/Commissioning) Guidance

- NHS England. Enhanced service specification: Weight management 2024/25. March 2024.
- NHS England. NHS Standard Contract for Severe and Complex Obesity – All Ages (A05/S/a). October 2013.
- NHS England. Clinical Commissioning Policy: Complex and Specialised Obesity Surgery. NHSCB/A05/P/a. April 2013.

Other Guidance

- UK Department of Health and Social Care. Tackling obesity: empowering adults and children to live healthier lives. July 2020.[29]
- Yumuk V, Tsigos C, Fried M, Schindler K, Busetto L, Micic D et al. European Guidelines for Obesity Management in Adults. December 2015.[30]
- Scottish Intercollegiate Guidelines Network. Management of Obesity – A national clinical guideline. 2010.[31]

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