Health Technology Briefing
July 2025

Semaglutide for treating type 2 diabetes in children and adolescents

Company/Developer	Novo Nordisk Ltd

☐ New Active Substance ☒ Significant Licence Extension (SLE)

NIHRIO ID: 30662	NICE ID: Not available	UKPS ID: N/A

Licensing and Market Availability Plans

Currently in phase III clinical development.

Summary

Semaglutide is currently in clinical development for treating type 2 diabetes mellitus (T2DM) in children and adolescents when their condition is not being controlled with current treatments. T2DM is a chronic condition where the body's cells become resistant to, or stop producing enough insulin, a hormone that helps to control the levels of glucose (sugar) in the blood. T2DM is increasingly seen in younger people who are at a much higher risk of developing diabetes complications such as heart disease or damage to the kidneys, eyes or nerves, compared to older adults. Some current treatment options for younger people have produced temporary therapeutic effect or the need for frequent dose adjustments which could result in poor adherence, hence the need for more effective longer acting therapies for this age group.

Semaglutide, is a 'GLP-1 receptor agonist'. It acts in the same way as GLP-1 (a hormone produced in the gut) by increasing the amount of insulin that the pancreas releases in response to food. This helps with the control of blood glucose levels. Semaglutide is administered orally once daily. If licensed, semaglutide would provide an additional treatment option for patients with T2DM.

Proposed Indication

Treatment of type 2 diabetes mellitus (T2DM) in paediatric and adolescent patients.[1]

Technology

Description

Semaglutide (Rybelsus) is a glucagon-like peptide-1 (GLP-1) analogue that acts as a GLP-1 receptor agonist which selectively binds to and activates the GLP-1 receptor. GLP-1 is a physiological hormone that has multiple actions in glucose and appetite regulation, and in the cardiovascular system. The glucose and appetite effects are specifically mediated via GLP-1 receptors in the pancreas and the brain. Semaglutide reduces blood glucose in a glucose dependent manner by stimulating insulin secretion and lowering glucagon secretion when blood glucose is high. The mechanism of blood glucose lowering also involves a minor delay in gastric emptying in the early postprandial phase. During hypoglycaemia, semaglutide diminishes insulin secretion and does not impair glucagon secretion. Semaglutide reduces body weight and body fat mass through lowered energy intake, involving an overall reduced appetite. In addition, semaglutide reduces the preference for high fat foods.[2]

Semaglutide is in development for the treatment of T2DM in paediatric and adolescent populations in combination with metformin or basal insulin or both. In the phase III clinical trial (NCT04596631, PIONEER TEENS) patients will receive semaglutide tablets or placebo once daily in addition to background treatment with metformin, basal insulin or both, in addition to diet and exercise.[1]

Key Innovation

In recent decades, there has been an increase in the number of children and adolescents being diagnosed with, and treated for, T2DM.[3] T2DM in adolescents has been seen to be more aggressive than adult T2DM, with a higher treatment failure rate and mortality.[4,5] To compound this, there are currently fewer glucose-lowering treatment options that have been approved for use in the treatment of adolescent T2DM in the UK compared to the adult population.[5] Adolescents with T2DM exhibit a faster rate of deterioration of β-cell function and greater extent of insulin resistance than adults with similar adiposity, presenting a decreased response to insulin sensitisers and a high therapeutic failure rate. Current therapies for treatment of T2DM have produced temporary therapeutic effects or the need for frequent dose adjustments.[5]

The primary advantage with oral semaglutide as compared with currently available GLP-1 treatment is that it is available for oral administration as compared with an injection.[6] This could improve adherence in a population that may be averse to injections. If licensed, oral semaglutide will offer an additional treatment option for children and adolescents with T2DM.

Regulatory & Development Status

Oral semaglutide currently has Marketing Authorisation in the EU/UK for:[2]

- treatment of adults with insufficiently controlled T2DM to improve glycaemic control as an adjunct to diet and exercise
    - as monotherapy when metformin is considered inappropriate due to intolerance or contraindications
    - in combination with other medicinal products for the treatment of diabetes.

Oral semaglutide is in phase III/II clinical development for:[7]

- Overweight and obesity
- Alzheimer's disease
- Nonalcoholic steatohepatitis

Patient Group

Disease Area and Clinical Need

T2DM is usually a lifelong condition that develops when the cells of the body become resistant to insulin, or the pancreas stops producing enough insulin. Insulin is a hormone produced in the pancreas that helps to regulate the levels of glucose in the blood.[8] The symptoms of T2DM often develop gradually over time and commonly include increased thirst, frequent urination, unintended weight loss, fatigue, blurred vision, slow healing of cuts or wounds. There are several risk factors associated with T2DM, including being overweight or obese, an inactive lifestyle, and a family history of T2DM.[9] Developing T2DM also increases the risk of developing serious problems of the eyes, feet, heart and nerves.[10] Younger people diagnosed with T2DM are at a much higher risk of developing diabetes complications as the condition is more aggressive compared to older adults. These complications can come on more quickly in children and young adults than in older adults.[11]

In UK, about 36,000 children and young people under the age of 19 years have diabetes, of which about 10% have T2DM (2019).[12] From a surveillance study conducted between April 2015 and April 2016, the UK incidence of T2DM was estimated at 0.72 per 100,000 children and young people per year.[12] In 2023-24, in England, there were 63,511 finished consultant episodes (FCE) for T2DM (ICD10 code E11), with 36,679 admissions resulting in 6,447 day cases and 283,054 FCE bed days.[13]

Recommended Treatment Options

The National Institute for Health and Care Excellence (NICE) recommend the following interventions for children and young people with T2DM:[14]

- Insulin therapy
- Metformin
- Liraglutide
- Dulaglutide
- Empagliflozin
- Dietary and lifestyle changes
- Surgery

Clinical Trial Information

Trial	**PIONEER TEENS**, NCT04596631, EudraCT 2018-002952-34; Efficacy and Safety of Oral Semaglutide Versus Placebo Both in Combination With Metformin and/or Basal Insulin in Children and Adolescents With Type 2 Diabetes **Phase III** – Active, not recruiting **Location(s):** Five EU countries, UK, USA and other countries **Primary completion date**: April 2025

Trial Design	Randomised, parallel assignment, quadruple masked, placebo-controlled
Population	N=132 (estimated); subjects with T2DM; aged 10 to 18 years.
Intervention(s)	Oral semaglutide once daily with metformin and/or basal insulin
Comparator(s)	Matched placebo
Outcome(s)	Primary outcome: • Change from baseline in glycosylated haemoglobin (HbA1c) [Time Frame: Week 0, week 26] See trial record for full list of other outcomes
Results (efficacy)	-
Results (safety)	-

Estimated Cost

Oral semaglutide is already marketed in the UK for the treatment of type 2 diabetes mellitus; packs of 30 3mg, 7mg and 14mg tablets cost £78.48.[15]

Relevant Guidance

NICE Guidance

- NICE technology appraisal in development. Canagliflozin for treating type 2 diabetes in people 10 to 17 years (TS ID 11888). Expected date of issue to be confirmed.
- NICE technology appraisal. Empagliflozin in combination therapy for treating type 2 diabetes (TA336). March 2015.
- NICE clinical guideline. Diabetes (type 1 and type 2) in children and young people: diagnosis and management (NG18). August 2015. Last updated: May 2023.
- NICE quality standard. Diabetes in children and young people (QS125). Last updated: March 2022.

NHS England (Policy/Commissioning) Guidance

- NHS England. Action for Diabetes. January 2014.
- NHS England. 2013/14 NHS Standard contract. Paediatric medicine: endocrinology and diabetes. E03/S/e.

Other Guidance

- Scottish Intercollegiate Guidelines Network (SIGN). Pharmacological management of glycaemic control in people with type 2 diabetes. 2017.[16]
- Scottish Intercollegiate Guidelines Network (SIGN). Management of diabetes. 2017.[17]

Additional Information

Novo Nordisk Ltd did not enter information about this technology onto the UK PharmaScan database; the primary source of information for UK horizon scanning organisations on new medicines in development.

As a result, the NIHR Innovation Observatory has had to obtain data from other sources.

UK PharmaScan is an essential tool to support effective NHS forward planning; allowing more effective decision making and faster uptake of innovative new medicines for patients who could benefit.

We urge pharmaceutical companies to use UK PharmaScan so that we can be assured of up-to-date, accurate and comprehensive information on new medicines.

References

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