

Northern (NHS) Treatment Advisory Group

Treatment Appraisal: Decision Summary

Date	1 st September 2020
Appraisal & Details	Oral semaglutide for the treatment of type 2 diabetes mellitus. The Northern (NHS) Treatment Advisory Group considered an appraisal of oral semaglutide for the treatment of type 2 diabetes mellitus.
Recommendation	The Northern (NHS) Treatment Advisory Group recommends oral semaglutide as an option for patients with type 2 diabetes mellitus who require intensification of treatment, if use of a glucagon-like peptide 1 receptor agonist (GLP1RA) is clinically appropriate, in line with licensing and relevant guidance, and if an oral option is preferred. However, in patients with pre-existing cardiovascular disease or at high risk of cardiovascular (CV) events an agent with proven efficacy for CV risk reduction may be more suitable.
Clinical evidence summary	Semaglutide (Rybelsus®▼, Novo Nordisk) is the first oral GLP1 receptor agonist (GLP1RA), indicated as an adjunct to diet and exercise for the treatment of adults with insufficiently controlled type 2 diabetes mellitus. A large phase III clinical trial programme found that semaglutide was generally associated with greater reductions in HbA1c, body weight and fasting plasma glucose than comparators, which included placebo, sitagliptin, empagliflozin, and liraglutide. The treatment differences against active comparators were not always clinically important. A cardiovascular (CV) outcomes trial found no difference between oral semaglutide and placebo for the compound risk of stroke, myocardial infarction and CV death compared to placebo in people with a history of CV disease or with CV risk factors but was not powered to assess whether oral semaglutide reduces CV risk.
Safety	The safety profile of oral semaglutide was in line with subcutaneous semaglutide, including an increased risk of diabetic retinopathy.
Patient Perspective	A literature review examining patient preference for drug formulation found that people with diabetes generally preferred oral to injectable preparations, although the difference was not always statistically significant. However, the same review found that patients also generally prefer less frequent dosing, meaning a weekly GLP1RA may be preferred. Individual preferences should therefore be discussed with the patient when selecting the most appropriate agent, bearing in mind that the comparative effectiveness of oral semaglutide has not been established against all available competitors. The requirement to take semaglutide on an empty stomach and at least 30 minutes before eating or taking other medicines may be challenging for some people, although the tablet can be taken at any time of day.



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Cost analysis summary	<p>In 2019 a total of 56.7 million items for diabetes were dispensed in England, at a total cost of £1.12 billion. The GLP1RAs accounted for around 2.4% of the items prescribed (1.3 million) and 11.3% of the spend (£126.7 million).</p> <p>The introduction of oral semaglutide is expected to be cost neutral if there is no change in prescribing patterns for the GLP1RAs. As a whole may be some cost impact for this class if they are used earlier in the treatment pathway than currently recommended by NICE, in order to reduce the rate of CV events.</p>
Financial impact PbR: in-tariff	<p>Oral semaglutide costs £78.48 per pack of 30 tablets (all strengths), or £952 per patient per year This is comparable to the other marketed GLP1RAs, which currently cost between £700 and £1,430 per patient per year</p>