NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Single Technology Appraisal

Sotagliflozin, in combination with insulin, for treating type 1 diabetes [ID1376]

Final scope

Remit/appraisal objective

To appraise the clinical and cost effectiveness of sotagliflozin within its marketing authorisation for treating type 1 diabetes.

Background

Type 1 diabetes results from the body's own immune system destroying the cells that make insulin. The inability to secrete insulin leads to high blood glucose levels (that is, hyperglycaemia) and other metabolic abnormalities, which have short and long‑term health consequences. Long-term complications include blindness, kidney failure, foot ulceration, amputation, premature heart disease, stroke and death. The risk of developing complications can be reduced by limiting tissue damage with insulin treatment that lowers blood glucose levels to as near normal levels as possible. However, insulin may increase the risk of hypoglycaemia (that is, low blood glucose levels) and weight gain. In addition, some people on insulin may still not meet blood glucose targets. In England in 2017, about 3.1 million people had diabetes[1], of which around 10% had type 1 diabetes[2].

The management of type 1 diabetes in adults includes structured education, dietary control, physical activity, self-monitoring of blood glucose levels, insulin therapy, hypoglycaemia control, ketone monitoring, control of cardiovascular risk and treating complications. The NICE clinical guideline on the diagnosis and management of type 1 diabetes in adults (NG17) recommends flexible basal-bolus insulin regimens. This involves self-injecting multiple daily doses of longer-acting insulin to keep blood glucose levels stable during periods of fasting, and short-acting insulin to prevent increases in blood glucose levels after meals. NICE technology appraisal 151 recommends continuous subcutaneous insulin infusion ('insulin pump') therapy for people on multiple daily injections who have disabling hypoglycaemia, or when average blood glucose concentrations remain high (haemoglobin A1c, HbA1c levels are 69 mmol/mol or higher). The clinical guideline also recommends consideration of adding metformin, which does not currently have a marketing authorisation in the UK for treating type 1 diabetes, to insulin therapy in some circumstances.

The technology

Sotagliflozin (Zynquista, Sanofi) is a dual SGLT1 and SGLT-2 inhibitor. SGLT-2 inhibitors prevent the kidneys from reabsorbing glucose into the blood, with

excess glucose removed in the urine. SGLT-1 predominately reduces glucose absorption within the gut. It is administered orally.

Sotagliflozin does not currently have a marketing authorisation in the UK for treating type 1 diabetes. Sotagliflozin in combination with insulin, is being studied in placebo-controlled trials for adults with type 1 diabetes that is inadequately controlled by insulin therapy alone.

Intervention(s)	Sotagliflozin in combination with insulin
Population(s)	Adults with type 1 diabetes on insulin therapy that does not adequately control blood glucose levels
Comparators	Insulin therapy with or without metformin
Outcomes	The outcome measures to be considered include: • HbA1c/glycaemic control/blood glucose variability • body mass index/change in body weight/waist circumference • frequency and severity of hypoglycaemia • changes in cardiovascular risk factors, including blood pressure and lipids • microvascular complications of diabetes, including damage to nerve, kidney and eye • macrovascular complications of diabetes including coronary artery disease, peripheral arterial disease, stroke and lower limb amputations • mortality • total daily insulin dose • adverse effects of treatment, including diabetic ketoacidosis, fractures, genital and urinary tract infections • health-related quality of life.
Economic analysis	The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year. The reference case stipulates that the time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared. Costs will be considered from an NHS and Personal

	Social Services perspective.
Other considerations	Guidance will only be issued in accordance with the marketing authorisation. Where the wording of the therapeutic indication does not include specific treatment combinations, guidance will be issued only in the context of the evidence that has underpinned the marketing authorisation granted by the regulator.
Related NICE recommendations and NICE Pathways	**Related Technology Appraisals** 'Continuous subcutaneous insulin infusion for the treatment of diabetes mellitus' (2008) NICE Technology Appraisal 151. Static list. **Appraisals in development** 'Dapagliflozin for type 1 diabetes' NICE technology appraisals guidance [ID1478]. Publication date to be confirmed. 'Empagliflozin for type 1 diabetes mellitus, adjunct to insulin' NICE technology appraisals guidance [ID1275]. Publication date to be confirmed. 'Diabetes – buccal insulin' NICE technology appraisals guidance [ID311]. Suspended. **Related Guidelines** 'Type 1 diabetes in adults: diagnosis and management' (2015) NICE guideline 17. Review date to be confirmed. **Related Interventional Procedures** 'Allogeneic pancreatic islet cell transplantation for type 1 diabetes mellitus' (2008) NICE interventional procedures guidance 257. **Related Quality Standards** 'Diabetes in adults' (2016) NICE quality standard 6. **Related NICE Pathways** 'Type 1 diabetes in adults' (2016) NICE Pathway.
Related National Policy	Department of Health (2016) NHS outcomes framework 2016 to 2017: Domains 1–5. NHS England (2017) Manual for Prescribed Specialised Services 2017/18. Chapter 68: Islet transplantation service (adults).

References

1. Diabetes UK (2017) Diabetes Prevalence 2017. Accessed November 2018.

2. Diabetes UK (2018) Facts & Figures. Accessed November 2018.