

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Health Technology Appraisal

Buccal insulin for the management of type 1 diabetes

Draft scope (Pre-referral)

Draft remit/appraisal objective

To appraise the clinical and cost effectiveness of buccal insulin within its licensed indication for the management of type 1 diabetes.

Background

Diabetes mellitus (diabetes) is a chronic metabolic disorder characterised by elevated blood glucose levels (hyperglycaemia) resulting from a lack of the hormone insulin or resistance to its action. If not controlled effectively, diabetes can lead to complications including kidney failure, blindness, limb amputation, coronary heart disease, stroke and damage to the nervous system, peripheral blood vessels and skin.

There are two major types of diabetes. Type 1 diabetes is due to an absolute loss of insulin production and therefore administration of insulin is necessary for survival. Type 2 diabetes results from reduced insulin production and/or reduced tissue sensitivity to insulin (known as insulin resistance).

There are approximately 2.5 million people in England and Wales with diabetes, approximately 10% of whom have type 1 diabetes.

NICE clinical guideline No. 15 recommends that management of type 1 diabetes should be a multidisciplinary approach involving a team with skills in education, nutrition, therapeutics, identification and management of complications, foot care, counselling and psychological care. Therapeutic management should be optimised towards attaining targets to prevent vascular complications. There are four categories of insulin available for use. These are rapid-acting insulin analogues (such as insulin aspart, insulin glulisine and insulin lispro), short-acting insulin, intermediate acting insulin and long-acting insulin analogues. In addition, insulin pumps are also in use. Insulin is destroyed by enzymes in the stomach so these forms of insulin are given by injection. Different combinations of these categories are adjusted according to the needs of the individual.

The technology

Buccal insulin (Oral-Lyn, Generex Biotechnology) is a short-acting formulation of human recombinant insulin that is sprayed into the oral cavity, where the insulin is absorbed into the bloodstream through the mucosal lining.

Buccal insulin does not currently have marketing authorisation in the UK. It is being studied in clinical trials, given in a split dose before and after meals, in

comparison with pre-prandial (before meal) short-acting soluble insulin in people with type 1 diabetes receiving NPH (isophane) intermediate-acting insulin. It has also been studied in comparison with short-acting insulin at meal time in adolescents with type 1 diabetes receiving glargine (a long-acting insulin analogue).

Intervention(s)	Buccal insulin
Population(s)	People with type 1 diabetes mellitus receiving intermediate-acting or long-acting insulin for whom prandial insulin is required
Comparators	Injectable short-acting insulin (soluble insulin) or short-acting insulin analogues such as insulin aspart, insulin glulisine and insulin lispro
Outcomes	<p>The outcome measures to be considered include:</p> <ul style="list-style-type: none"> • mortality • frequency and severity of symptomatic hypoglycaemic episodes • incidence of diabetic emergencies such as diabetic ketoacidosis requiring hospitalisation • frequency of occlusive vascular events or microvascular complications • measures of glycaemic control • adverse effects of treatment • health-related quality of life
Economic analysis	<p>The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year.</p> <p>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.</p> <p>Costs will be considered from an NHS and Personal Social Services perspective.</p>
Other considerations	Guidance will only be issued in accordance with the marketing authorisation

<p>Related NICE recommendations</p>	<p>Related Technology Appraisals:</p> <p>Technology appraisal No. 151, July 2008. 'Continuous subcutaneous insulin infusion for the treatment of diabetes (review).' Expected review date: February 2011.</p> <p>Technology appraisal No. 53, December 2002 'The clinical effectiveness and cost effectiveness of long acting insulin analogues for diabetes.' (To be reviewed within the update of CG15).</p> <p>Related Guidelines:</p> <p>Clinical guideline No. 63, March 2008 'Diabetes in pregnancy: management of diabetes and its complications from pre-conception to the postnatal period.' Expected review date: March 2011.</p> <p>Clinical guideline No. 15, July 2004, 'Diagnosis and management of type 1 diabetes in children, young people and adults.'</p> <p>Related Interventional Procedures:</p> <p>Interventional procedures guidance No. 257. .April 2008 'Allogeneic pancreatic islet cell transplantation for type 1 diabetes mellitus.'</p>
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Questions for consultation

Have the most appropriate comparators for the treatment of type 1 diabetes been included in the scope? Are the comparators listed routinely used in clinical practice?

Has the population been appropriately defined? Should patients with type 2 diabetes also be considered?

Are there any subgroups of patients in whom the technology is expected to be more clinically effective and cost effective or other groups that should be examined separately?

Are there any issues that require special attention in light of the duty to have due regard to the need to eliminate unlawful discrimination and promote equality?

NICE intends to appraise this technology through its Single Technology Appraisal (STA) Process. We welcome comments on the appropriateness of appraising this topic through this process. (Information on the Institute's

Technology Appraisal processes is available at
http://www.nice.org.uk/aboutnice/howwework/devnicetech/technologyappraisalprocessguides/technology_appraisal_process_guides.jsp)