NICE gives green light to prolonged-release exenatide for type 2 diabetes in final draft guidance

London, England (January 13, 2012) - In final draft guidance published today (Friday 13 January) NICE, the healthcare guidance body, has confirmed its initial draft recommendation of prolonged-release exenatide for people with type 2 diabetes, when control of blood glucose remains or becomes inadequate (HbA1c of 7.5% or above, or other higher level agreed with the individual), and the person has:

- a body mass index (BMI) of 35 kg/m² or higher in those of European family origin (with appropriate adjustment for other ethnic groups) and specific psychological or medical problems associated with high body weight, or
- a BMI below 35 kg/m², and therapy with insulin would have significant occupational implications or weight loss would benefit other significant obesity-related comorbidities.

Treatment with prolonged-release exenatide in a triple therapy regimen should only be continued if a beneficial metabolic response has been shown.

Prolonged-release exenatide in dual therapy regimens (in combination with metformin or a sulphonylurea) is recommended as a treatment option in people with type 2 diabetes, only if:

- the person is intolerant of either metformin or a sulphonylurea, or treatment with metformin or a sulphonylurea is contraindicated, and
- the person is intolerant of thiazolidinediones and dipeptidyl peptidase-4 (DPP-4) inhibitors, or treatment with thiazolidinediones and DPP-4 inhibitors is contraindicated.

Treatment with prolonged-release exenatide in a dual therapy regimen should only be continued if a beneficial metabolic response has been shown.

Exenatide improves glycaemic control in patients with type 2 diabetes in a number of ways, including: enhanced pancreatic insulin and glucagon secretion, which helps to control blood sugar levels; reduced food intake; reduced weight; and delayed gastric emptying. The prolonged-release suspension is injected once weekly, as opposed to twice a day for the conventional formulation.
Professor Carole Longson, Health Technology Evaluation Centre Director at NICE said: "2.25 million people in the UK are affected by Type 2 diabetes. It is important that people are offered effective treatment options, and NICE’s recommendations are intended to help patients and providers make the best decisions to improve patient outcomes."

NICE has not yet issued final guidance to the NHS; registered stakeholders now have the opportunity to appeal against these draft recommendations and consequently they may change in the event of an appeal being received.

Until NICE issues final guidance, NHS bodies should make decisions locally on the funding of specific treatments. Once NICE issues its guidance on a technology it replaces local recommendations across the country.

Final guidance is likely to be published in February 2012.

References

i. Metformin, sulphonylureas and thiazolidinediones are other drugs that can assist in the management of age 2 diabetes and insulin. They have various effects on the body

ii. The HbA1c test indicates blood glucose levels for the previous two to three months. HbA1c measures the amount of glucose that is being carried by the red blood cells to the body.

iii. This is defined as a reduction of at least 1 percentage point in HbA1c and a weight loss of at least 3% of initial body weight at 6 months, and as described in Type 2 diabetes - the management of type 2 diabetes (NICE clinical guideline 87).

iv. DPP-4 inhibitors lower blood sugar levels by blocking an enzyme known as dipeptidyl peptidase IV (DPP-4), which is responsible for degrading the gut hormones that stimulate the insulin-producing cells, and slow gastric emptying time after a meal.

v. And as described in Liraglutide for the treatment of type 2 diabetes mellitus, (NICE technology guidance 203).

vi. Glucagon is a hormone secreted by the pancreas which raises blood glucose levels. Its effect is opposite that of insulin, which lowers blood glucose levels.

vii. NICE has only appraised prolonged-release exenatide in this guidance. The conventional formulation of exenatide is covered in Type 2 diabetes - the management of type 2 diabetes (NICE clinical guideline 87).

viii. Diabetes UK.
1. The final appraisal determination document can be found from Friday 13 January on the NICE website at:

   [http://guidance.nice.org.uk/TA/Wave22/0](http://guidance.nice.org.uk/TA/Wave22/0)

   The deadline for receipt of appeals and requests for changes is Friday 27 January at 5:00pm.

2. Subject to any appeal of the FAD by consultees, NICE will produce final guidance on the use of prolonged-release exenatide in the NHS in England and Wales. For further details on developing technology appraisals, see the NICE website at:

   [http://www.nice.org.uk/aboutnice/howwework/devnicetech/developing_nice_technology_appraisals.jsp](http://www.nice.org.uk/aboutnice/howwework/devnicetech/developing_nice_technology_appraisals.jsp)

3. Exenatide prolonged release suspension for injection (Bydureon, Eli Lilly) has a UK marketing authorisation for the treatment of type 2 diabetes mellitus in adults to achieve glycaemic control in combination with:

   - metformin
   - a sulphonylurea
   - a thiazolidinedione
   - metformin and a sulphonylurea
   - metformin and a thiazolidinedione.

   in adults who have not achieved adequate glycaemic control on maximally tolerated doses of these oral therapies. The recommended dose is 2 mg exenatide once weekly by subcutaneous injection.
4. Exenatide is a glucagon-like peptide-1 (GLP-1) receptor agonist. Incretin hormones like GLP-1 enhance glucose-dependent insulin secretion, and reduced glucose-dependent glucagon secretion.

5. Prolonged-release exenatide costs £73.36 for a pack of four single-dose kits containing one vial of exenatide 2 mg. The specific cost of different batches can vary due to manufacturer submission and procurement discount variations. Costs may vary in different patient groups, but are often provided via manufacturer submission.

About NICE

1. The National Institute for Health and Clinical Excellence (NICE) is the independent agency responsible for producing, reviewing and updating guidance on the promotion of good health and the prevention and treatment of ill health.

2. NICE produces guidance in three areas of health:
   - Public Health - guidance on the promotion of good health and the prevention of ill health for those working in the NHS, local authorities and the wider public and voluntary sector
   - Health Technologies - guidance on the use of new and existing medicines, treatments, medical technologies (including devices and diagnostics) and procedures within the NHS
   - Clinical Practice - guidance on the appropriate treatment and care of people with specific diseases and conditions within the NHS

3. NICE produces standards for patient care:
   - Quality Standards - these reflect the very best in high-quality patient care, to help healthcare practitioners and commissioners of care deliver excellent services

4. NICE produces guidance in three areas of health:
   - Public Health - guidance on the promotion of good health and the prevention of ill health for those working in the NHS, local authorities and the wider public and voluntary sector
   - Health Technologies - guidance on the use of new and existing medicines, treatments, medical technologies (including devices and diagnostics) and procedures within the NHS
   - Clinical Practice - guidance on the appropriate treatment and care of people with specific diseases and conditions within the NHS
Quality and Outcomes Framework - NICE develops the clinical and health improvement indicators in the QOF, the Department of Health’s clinical tools that help GPs and other healthcare professionals improve patient care through evidence-based guidance, research and information to help health professionals deliver the best patient care through NHS Evidence.

This page was last updated: 12 January 2012

National Institute for Health and Clinical Excellence (NICE), 13.01.2012 (tB).