NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Insulin efsitora alfa for treating type 2 diabetes ID6499

Draft scope

Draft remit/evaluation objective

To appraise the clinical and cost effectiveness of insulin efsitora alfa within its marketing authorisation for treating type 2 diabetes.

Background

Diabetes mellitus 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. Type 2 diabetes results from reduced insulin secretion or reduced tissue sensitivity to insulin (known as insulin resistance)[1]. If not managed effectively, diabetes mellitus can lead to kidney failure, blindness, foot problems, and damage to the nervous system[2]. People with diabetes are also more at risk of cardiovascular disease[3].

There were 4.6 million people in the UK with diagnosed diabetes mellitus in 2023-24, of which around 90% had type 2 diabetes[4]. Additionally, it is estimated that over 1.2 million people have undiagnosed type 2 diabetes[4]. People from Black African, African Caribbean and South Asian family backgrounds are at a higher risk of developing type 2 diabetes from a younger age[5].

NICE's guideline on type 2 diabetes in adults: management (NG28) recommends reinforcing advice on diet, lifestyle and adherence to drug treatment for all people with type 2 diabetes.

If blood glucose levels are not controlled by diet and exercise alone, NG28 recommends the following first-line drug treatment:

- Standard-release metformin.
- For people with chronic heart failure, atherosclerotic cardiovascular disease or at high risk of cardiovascular disease: a dual therapy of a selective sodium glucose-cotransporter 2 (SGLT2) inhibitor with proven cardiovascular benefit and metformin.
- If metformin is contraindicated or not tolerated for people with chronic heart failure, atherosclerotic cardiovascular disease or at high risk of cardiovascular disease: an SGLT2 inhibitor with proven cardiovascular benefit.
- If metformin is contraindicated or not tolerated for people who are not at risk of or without cardiovascular disease: a dipeptidyl peptidase-4 (DPP-4) inhibitor, pioglitazone, or a sulfonylurea.
- If a DPP-4 inhibitor would otherwise be prescribed and a sulfonylurea or pioglitazone is not appropriate: an SGLT2 inhibitor such as canagliflozin, dapagliflozin, and empagliflozin (TA390) or ertugliflozin (TA572).

When there is inadequate glycaemic control following first-line monotherapy, NG28 recommends adding one of the following treatment options:

- A DPP-4 inhibitor, pioglitazone or a sulfonylurea.
- For people taking metformin and a sulfonylurea is contraindicated or not tolerated or the person is at significant risk of hypoglycaemia or its consequences: a SGLT2 inhibitor (canagliflozin [TA315], ertugliflozin [TA572], dapagliflozin [TA288] or empagliflozin [TA336]).

If there is inadequate glycaemic control with dual therapy, NG28 recommends either:

- Triple therapy by adding a DPP-4 inhibitor, pioglitazone or a sulfonylurea, or
- For people taking metformin and a sulfonylurea: triple therapy by adding a SGLT2 inhibitor (canagliflozin [TA315], dapagliflozin [TA418], empagliflozin [TA336]), or
- For people taking metformin and a thiazolidinedione: triple therapy by adding a SGLT2 inhibitor (canagliflozin [TA315], empagliflozin [TA336]), or
- For people taking metformin and a DPP-4 inhibitor which inadequately controls disease and for whom a sulfonylurea or pioglitazone is not appropriate: triple therapy by adding ertugliflozin (TA583), or
- Insulin-based treatment

If metformin is contraindicated or not tolerated and dual therapy with 2 oral drugs has provided inadequate control, NG28 recommends:

- Insulin-based treatment

If triple therapy with metformin and 2 other oral drugs is not effective, not tolerated or contraindicated, triple therapy by switching one drug for a GLP-1 mimetic (such as dulaglutide, exenatide, liraglutide, lixisenatide, semaglutide, or tirzepatide [TA924]) is recommended for some people.

The technology

Insulin efsitora alfa (brand name unknown, Eli Lilly) does not currently have a marketing authorisation in the UK for treating type 2 diabetes. It has been studied in clinical trials compared with insulin glargine and insulin degludec in people with type 2 diabetes who were insulin naïve and those who received insulin daily.

Intervention(s)	Insulin efsitora alfa, alone, or alongside other treatments for type 2 diabetes
Population(s)	People with type 2 diabetes, suitable for basal insulin therapy

Subgroup(s)	If the evidence allows, the following subgroup may be considered: • People who are insulin naïve • People who have previously had insulin
Comparators	Basal insulin therapy, alone, or alongside other treatments for type 2 diabetes
Outcomes	The outcome measures to be considered include: • change in HbA1c • HbA1c and glycaemic control • frequency and severity of hypoglycaemia • weekly basal insulin dose • body mass index, body weight, waist circumference • cardiovascular risk factors, including blood pressure and lipid levels • 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 • adverse effects of treatment • 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. The availability of any commercial arrangements for the intervention, comparator and subsequent treatment technologies will be taken into account. The availability of any managed access arrangement for the intervention will be taken into account. The availability and cost of biosimilar and generic products should be taken into account.

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	**Related technology appraisals:** Tirzepatide for treating type 2 diabetes (2023) NICE technology appraisal guidance 924 Ertugliflozin with metformin and a dipeptidyl peptidase-4 inhibitor for treating type 2 diabetes (2019) NICE technology appraisal guidance 583 Ertugliflozin as monotherapy or with metformin for treating type 2 diabetes (2019) NICE technology appraisal guidance 572 Dapagliflozin in triple therapy for treating type 2 diabetes (2016) NICE technology appraisal guidance 418 Canagliflozin, dapagliflozin and empagliflozin as monotherapies for treating type 2 diabetes (2016) NICE technology appraisal guidance 390 Empagliflozin in combination therapy for treating type 2 diabetes (2015) NICE technology appraisal guidance 336 Canagliflozin in combination therapy for treating type 2 diabetes (2014) NICE technology appraisal guidance 315 Dapagliflozin in combination therapy for treating type 2 diabetes (2013, updated 2016) NICE technology appraisal guidance 288 Continuous subcutaneous insulin infusion for the treatment of diabetes mellitus (2008) NICE technology appraisal guidance 151 **Related NICE guidelines:** Type 2 diabetes in adults: management (2015, updated 2022) NICE guideline 28. **Related NICE guidelines in development:** Type 2 diabetes in adults: management (medicines update). NICE guideline. Publication to be confirmed **Related quality standards:** Type 2 diabetes in adults (2023) NICE quality standard 209

Questions for consultation

Where do you consider insulin efsitora alfa will fit into the existing care pathway for type 2 diabetes?

Would insulin efsitora be used instead of any other treatments for type 2 diabetes, other than basal insulin therapy?

Which other treatments would insulin efsitora be used alongside?

Which basal insulin therapies are available in the NHS?

Which basal insulin therapies are typically used in the NHS?

Please select from the following, will insulin efsitora alfa be:
A. Prescribed in primary care with routine follow-up in primary care
B. Prescribed in secondary care with routine follow-up in primary care
C. Prescribed in secondary care with routine follow-up in secondary care
D. Other (please give details):
For comparators and subsequent treatments, please detail if the setting for prescribing and routine follow-up differs from the intervention.

Would insulin efsitora alfa be a candidate for managed access?

Do you consider that the use of insulin efsitora alfa can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation?

Please identify the nature of the data which you understand to be available to enable the committee to take account of these benefits.

Please indicate if any of the treatments in the scope are used in NHS practice differently than advised in their Summary of Product Characteristics. For example, if the dose or dosing schedule for a treatment is different in clinical practice. If so, please indicate the reasons for different usage of the treatment(s) in NHS practice. If stakeholders consider this a relevant issue, please provide references for data on the efficacy of any treatments in the pathway used differently than advised in the Summary of Product Characteristics.

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that the proposed remit and scope may need changing in order to meet these aims. In particular, please tell us if the proposed remit and scope:

- could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which insulin efsitora alfa will be licensed;

- could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the technology;

- could have any adverse impact on people with a particular disability or disabilities.

Please tell us what evidence should be obtained to enable the committee to identify and consider such impacts.

NICE intends to evaluate this technology through its Single Technology Appraisal process. (Information on NICE's health technology evaluation processes is available at https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/changes-to-health-technology-evaluation).

References

1. NHS. What is type 2 diabetes?. Accessed August 2025

2. Diabetes UK. Complications of diabetes. Accessed August 2025

3. Diabetes UK. Diabetes and heart disease. Accessed August 2025

4. Diabetes UK. How many people in the UK have diabetes? Accessed August 2025

5. Diabetes UK. Ethnicity and type 2 diabetes. Accessed August 2025