Content of this Plain Language Summary

The objective of the Plain Language Summary is to help the general public understand EUnetHTA assessments. You can find the link to the full assessment report later in the summary.

What is included in this Plain Language Summary? First, this document explains what EUnetHTA is and what this network does. Second, you will find the summary of the assessment. You can use the table of content to immediately go to the summary of the assessment.

What is EUnetHTA?

EUnetHTA is the European Network for Health Technology Assessment (HTA). EUnetHTA was established to create an effective and sustainable network for HTA across Europe. Our partners work together to help develop information to contribute to HTA in European countries. For more information on our goals and how we work, please visit our website and our patient flyer.

EUnetHTA consists of over 80 partners that are all non-profit organisations. All partner organisations either produce or support the production of Health Technology Assessment reports. For more information on Health Technology Assessment, visit EUnetHTA's Frequently Asked Questions.

EUnetHTA does not give any advice on reimbursement of a specific health technology. The reimbursement decision is a national or regional decision. This means that reimbursement of health technologies can also differ between countries in Europe.

What does EUnetHTA do?

EUnetHTA supports national and regional research institutions and health ministries in their decision-making. For this task, EUnetHTA uses specific methods to assess health technologies. Health technologies that may be assessed by EUnetHTA include medicines and other health technologies such as specialist medical care, surgical interventions and diagnostic tests. The purpose of this plain language summary is to help the general public understand the findings from this assessment.

SUMMARY OF THE ASSESSMENT

SOTAGLIFLOZIN FOR TREATING ADULTS WITH TYPE 1 DIABETES WHO HAVE A HIGH BMI

This section provides a summary of the assessment and was published on 23/06/2020. To get a better understanding of commonly used HTA concepts, we advise you to look at the HTAi glossary.

Why did we conduct this assessment?

The purpose of this EUnetHTA assessment is to give national healthcare systems robust information about the therapy under assessment.

What is the context of this assessment?

In 2017, almost 50 million adults were estimated to be living with Type 1 diabetes globally. Currently, there is no available cure. Type 1 diabetes is a disease in which the body is unable to produce insulin. This results in a buildup of blood sugar in the blood stream. In the long-term, this can result in diabetes-related complications such as severe eye or kidney problems, heart attacks, or strokes. In the short-term, extremely low and extremely high blood sugar levels can both be life-threatening.

Insulin is the mainstay of treatment for patients with Type 1 diabetes. Intensive insulin therapy is usually needed for patients to control their blood sugar levels. However this can cause weight gain and hypoglycaemia, and yet up to 70% of patients still often experience abnormally high (uncontrolled) blood sugar levels.

Adding sotagliflozin to insulin treatment may achieve lower blood sugar levels compared to insulin treatment alone. Sotagliflozin was granted a licence in April, 2019 for the treatment of patients with Type 1 diabetes who have a BMI of greater than 27 kg/m2 to improve glycaemic control together with insulin. It is an oral treatment and the dosage is 200 or 400 mg once daily as an addition to insulin therapy.

What did EUnetHTA review?

Through this assessment, EUnetHTA reviewed the clinical effectiveness and safety of a drug treatment. The purpose of this assessment was to review the effectiveness and safety of sotagliflozin added to insulin treatment compared to insulin treatment alone, i.e. how well the drug works compared to what is currently used to manage the condition.

What is the drug under review?	Sotagliflozin – when added to insulin treatment
What is the study group?	Adult patients with Type 1 diabetes who have a high BMI

What is the drug compared to?	• Insulin treatment alone
	• Two other drugs from the same class/family as sotagliflozin
	  ○ dapagliflozin
	  ○ empagliflozin

What are the outcomes this review investigates?	<u>Outcomes on effectiveness of the drug:</u> • well controlled blood sugar, and • no short-term complications • Quality of life <u>Outcomes on safety and side effects of the drug:</u> • Experiencing symptoms related to abnormally low blood sugar levels • Abnormally low blood sugar levels resulting in loss of consciousness • Buildup of toxic acids (ketones) in the blood

What are the main findings?

This evaluation found that sotagliflozin, when added to insulin therapy, worked as well as insulin therapy alone.

Adding sotagliflozin to insulin treatment:

- reduces the average blood sugar level over a period of 1 year;
- may lead to less frequent occurrence of abnormally low blood sugar levels that result in physical symptoms;
- can more frequently lead to the development of a potentially life-threatening buildup of toxic acids (ketones) in the blood. Although this risk can be partially managed, it is difficult to predict the extent of this problem in actual clinical practice. The risk of building up toxic acids can be managed through proper health care, patient education and self-monitoring;

It is highly uncertain whether sotagliflozin in either dosage improves a person's quality of life because the certainty of the evidence is very low.

Furthermore, the EUnetHTA evaluation compared sotagliflozin to dapagliflozin or empagliflozin in adults with Type 1 diabetes. Each of these drugs is prescribed in addition to insulin treatment. While the evidence isn't conclusive, sotagliflozin is unlikely to be better than dapagliflozin or empagliflozin on the outcomes considered.

Did EUnetHTA involve stakeholders?

EUnetHTA values involvement of stakeholders in the assessments. This ensures the assessments reflect patients' experiences and current practice. Patient associations were invited to provide input at the initial stage of this assessment. Their input was gathered via the open call for patient input. Input from two patient organisations was used to inform the selection of outcomes. Medical specialists were also invited to provide input on this assessment.

Additional information

This report was written by HTA organizations in Sweden (TLV), the Netherlands (ZIN), and Ireland (NCPE). Organizations from Spain (AEMPS), Switzerland (SNHTA), Lithuania (NVD), Portugal (INFARMED) and Poland (AOTMiT) have contributed in reviewing roles. The full scientific content is reported in the EUnetHTA assessment PTJA04 on sotagliflozin and can be found here.

If you have further questions, please contact: WP4_Pharmaceuticals@zinl.nl

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