Albiglutide in type 2 diabetes: Hint of minor added benefit

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Albiglutide (trade name Eperzan) has been approved since March 2014 for adults with type 2 diabetes mellitus in whom diet and exercise alone do not provide adequate glycaemic control. The German Institute for Quality and Efficiency in Health Care (IQWiG) examined in a dossier assessment whether the drug offers an added benefit over the appropriate comparator therapies in these patient groups.

According to the findings, there is a hint of a minor added benefit of albiglutide plus metformin in comparison with metformin plus sulfonylurea because hypoglycaemia occurs less frequently.

Subindications result in four research questions

Albiglutide is approved as monotherapy for patients who do not tolerate metformin. It is approved as add-on therapy in combination with other blood-glucose lowering drugs including insulin when these, together with diet and exercise, do not provide adequate glycaemic control. Albiglutide is injected under the skin once a week with a single use pen injector.

The Federal Joint Committee (G-BA) specified different appropriate comparator therapies for the subindications, resulting in a total of four comparisons: albiglutide as monotherapy versus a sulfonylurea (A), in combination with another blood-glucose lowering drug also in comparison with metformin and sulfonylurea (B), in combination with at least two other blood-glucose lowering drugs in comparison with

metformin and human insulin (C) and in combination with insulin also in comparison with metformin plus human insulin (D).

No studies submitted for three research questions

However, the drug manufacturer presented no relevant data for research questions A, C, and D. An added benefit of albiglutide versus the appropriate comparator therapies is therefore not proven in these cases.

No differences in mortality, morbidity and severe side effects

For research question B, the manufacturer presented one study (HARMONY 3), in which treatment with albiglutide plus metformin was compared with treatment with metformin in combination with the sulfonylurea glimepiride.

There were no statistically significant differences between the treatment groups with regard to the outcomes "morbidity", "symptoms" and "late complications" (e.g. stroke, cardiac morbidity). However, the study was also not designed to uncover differences in these outcomes. There were also no statistically significant differences in the outcomes "severe hypoglycaemia" or "serious side effects" and "discontinuations due to side effects". Data on health-related quality of life were not recorded in the study. Hence no added benefit of albiglutide is proven for these outcomes.

Results on hypoglycaemic events are uncertain

There were far fewer symptomatic hypoglycaemic events, which are associated with low blood glucose levels, in the albiglutide arm than in the glimepiride arm. Particularly in the beginning of the study,

symptomatic hypoglycaemia occurred more frequently under glimepiride. However, a fixed starting dose of 2 mg glimepiride was envisaged in the study, and an increase to 4 mg for the next step, whereas the approval also allows a starting dose of 1 mg and 1 mg steps for individual dose adjustment in the course of the treatment. Hence at least some of the patients probably received glimepiride doses that were too high, which may have led to hypoglycaemia. The study results on hypoglycaemia are therefore uncertain and the probability of the added benefit is only a hint.

Positive effect outweighs negative effect

The positive effect in symptomatic hypoglycaemia is in contrast to a negative effect in form of more frequent reactions at the injection site of albiglutide. This negative effect does not outweigh the positive effect, however. Overall, there is a hint of a minor added benefit of albiglutide in combination with metformin versus the appropriate comparator therapy.

G-BA decides on the extent of added benefit

The dossier assessment is part of the overall procedure for early benefit assessments according to the Act on the Reform of the Market for Medicinal Products (AMNOG) supervised by the G-BA. After publication of the manufacturer's dossier and IQWiG's assessment, the G-BA conducts a commenting procedure, which may provide further information and result in a change to the benefit assessment. The G-BA then decides on the extent of the added benefit, thus completing the early benefit assessment.

More information: www.iqwig.de/download/A14-36_A … ertung-35a-SGB-V.pdf

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