Type 2 diabetes: Added benefit of canagliflozin plus metformin is not proven

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The fixed combination of canagliflozin with metformin (trade name: Vokanamet) has been approved since April 2014 for adults with type 2 diabetes mellitus in whom diet and exercise do not provide adequate glycaemic control. The German Institute for Quality and Efficiency in Health Care (IQWiG) now examined in a dossier assessment whether the new drug combination offers an added benefit over the appropriate comparator therapy. No such added benefit can be derived from the dossier, however, because the manufacturer did not present any suitable data for any of the possible subindications.

IQWiG already came to the same conclusion in the assessment of canagliflozin as monotherapy and in various free combination therapies in June 2014.

Combination with further drugs possible

The fixed combination of canagliflozin and metformin can be used alone or in addition to other blood-glucose lowering drugs (including insulin) when these do not provide adequate glycaemic control. It is also an option for patients already taking the two drugs as separate tablets.

G-BA specifies appropriate comparator therapy

The Federal Joint Committee (G-BA) specified different appropriate comparator therapies for three possible different subindications: When

the fixed combination is used alone, it is to be compared with the combination of a sulfonylurea (glibenclamide or glimepiride) in combination with metformin. When the fixed combination is used together with a sulfonylurea or insulin, human insulin plus metformin is to be the appropriate comparator therapy.

No added benefit claimed for two subindications

The manufacturer claimed no added benefit for the combination with insulin and the combination with a sulfonylurea because the available studies allowed neither direct nor indirect comparisons.

Comparison not only of drugs, but also of therapeutic strategies

For the comparison of canagliflozin plus metformin with a sulfonylurea in free combination with metformin, the manufacturer used data from an approval study (DIA3009) that it had already submitted for the first dossier assessment.

These data are inadequate for the derivation of an added benefit, however. Because of its design, this study not only compared the effects of two drugs with each other, but also two different therapeutic strategies. Hence possible differences in treatment results cannot be clearly attributed to the drugs or the therapeutic strategies.

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/A14-27_C … ertung-35a-SGB-V.pdf

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