Vildagliptin for type 2 diabetes: No suitable data for combination with sulfonylurea

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Vildagliptin (trade name Galvus or Jalra) has been approved since September 2007 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) examined in a new dossier assessment whether this drug offers an added benefit over the appropriate comparator therapy. Such an added benefit cannot be derived from the new dossier either, however, because the drug manufacturer did not submit any suitable data.

Manufacturer itself applied for a new dossier assessment

Neither the first dossier assessment from July 2013 nor the assessment of the manufacturer's data subsequently submitted from October 2013 resulted in an advantage of vildagliptin for any of the possible therapeutic indications. Referring to results of one further study, which have become available in the meantime, the manufacturer applied to the Federal Joint Committee (G-BA) for a new dossier assessment for the combination with a sulfonylurea.

Blood-glucose lowering to near-normal levels only in the control arm

In its new dossier, the manufacturer referred to the results of a randomized controlled trial (BENEFIT), which compared vildagliptin

with NPH insulin, i.e. with a long-acting insulin based on human insulin, and in which all patients additionally received the sulfonylurea glimepiride.

However, the two study arms not only differed with regard to the 2 drugs: In the insulin arm, but not in the vildagliptin arm, the dose was continuously adjusted so that near-normal blood glucose levels were achieved. As a consequence, the HbA1c value in patients in the insulin arm was notably lower than in the vildagliptin arm. HbA1c is an indicator of long-term glycaemic control and is thought of as the "memory" of blood-glucose Levels.

Effect cannot be clearly attributed to drug

Due to its design, the BENEFIT study not only compared two drugs, but two therapeutic strategies. It is uncertain that the effects observed are attributable to the drugs used. They might instead have been caused by the therapeutic strategy alone. This is particularly the case for hypoglycaemias because their occurrence depends on the HbA1c value.

The data presented by the manufacturer cannot be interpreted in a meaningful way and are therefore inadequate for the derivation of an added benefit.

G-BA decides on the extent of added benefit

This dossier assessment is part of the early benefit assessment according to the Act on the Reform of the Market for Medicinal Products (AMNOG) supervised by the G-BA. After publication of the dossier assessment, the G-BA conducts a commenting procedure and makes a final decision on the extent of the added benefit.

More information: www.iqwig.de/download/A14-46_V … ertung-35a-SGB-V.pdf