Dulaglutide in type 2 diabetes: Hint of added benefit with short-acting insulin

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Since 2014 dulaglutide has been approved alone or in combination with other drugs for the treatment of adults with type 2 diabetes. The German Institute for Quality and Efficiency in Health Care (IQWiG) examined in a dossier assessment whether this new drug offers an added benefit over the appropriate comparator therapies.

IQWiG found a hint of minor added benefit for the combination with short-acting insulin with or without metformin. In contrast, an added benefit of dulaglutide versus the respective appropriate comparator therapy is not proven for the combination with long-acting insulin, for monotherapy, and for combinations with one or two oral antidiabetics.

Combination with metformin: positive and negative effects are balanced

Metformin plus sulfonylurea is the appropriate comparator therapy for the combination of dulaglutide with an oral antidiabetic. The drug manufacturer combined dulaglutide with metformin; it presented no data for combinations with other oral antidiabetics. It conducted an indirect comparison of two studies. For some of the outcomes investigated, there were no relevant data or there were no statistically significant differences between the treatment arms.

In the outcome category of non-serious and non-severe side effects, there were both positive and negative effects, which outweighed each

other: A hint of considerably lesser harm of the dulaglutide-metformin combination in confirmed symptomatic hypoglycaemia was offset by hints of considerably greater harm in nausea, vomiting and diarrhoea.

Dulaglutide in combination with short-acting insulin: advantages predominate

For the comparison between dulaglutide plus insulin (with or without an oral antidiabetic) and metformin plus human insulin, the manufacturer presented data from the AWARD-4 study, in which short-acting insulin was combined with dulaglutide. There were also both positive and negative effects. However, the negative effects - such as nausea or vomiting - all belonged to the outcome category of non-serious and non-severe events. Hence they do not completely raise doubts about the positive effect in serious adverse events, but weaken it. No sufficient data were available on micro- and macrovascular late complications. Due to a lack of data, also no conclusion can be drawn on the combination with a long-acting insulin.

No conclusion on added benefit can be drawn for two further research questions

Dulaglutide was to be compared with a sulfonylurea for monotherapy of patients in whom diet and exercise alone do not provide adequate glycaemic control. In its dossier, the manufacturer presented no data that were relevant for this research question so that the advantages and disadvantages of the treatments could not be compared.

For the combination of dulaglutide with two oral antidiabetics, the manufacturer conducted an indirect comparison between dulaglutide, metformin and glimepiride on one side, and a combination of metformin and human insulin on the other side. However, the two studies it used for

this comparison differed so greatly regarding the common comparator and the study populations that no conclusion on an added benefit of the dulaglutide combination could be derived from it.

Hence a hint of a minor added benefit of the new drug in combination with short-acting insulin remains.

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 Federal Joint Committee (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/A15-07_K … ertung-35a-SGB-V.pdf

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