Gliptins: IQWiG assessed data subsequently submitted by the manufacturer

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The German Institute for Quality and Efficiency in Health Care (IQWiG) analysed additional data on drugs from the group of gliptins. The drug manufacturers had subsequently submitted these data to the Federal Joint Committee (G-BA) in the commenting procedure. The Institute came to a different conclusion on the fixed combination of sitagliptin/metformin: As for the single agent sitagliptin before, there are now hints of an added benefit for this fixed combination. However, IQWiG still does not see any advantages of vildagliptin and the fixed combination of vildagliptin and metformin versus current standard treatment.

First assessment: hints of added benefit only for sitagliptin

Gliptins are drugs used for the treatment of people with type 2 diabetes mellitus who cannot sufficiently lower their high levels of blood glucose with dietary changes and exercise alone or do not tolerate other oral antidiabetics. In its dossier assessment of gliptins according to the Act on the Reform of the Market for Medicinal Products (AMNOG) on 1 July 2013, IQWiG concluded that there were hints of an added benefit solely for sitagliptin as a single agent. This applied to the therapeutic indication "sitagliptin plus metformin" in comparison with a sulfonylurea plus metformin.

Metformin dose not in compliance with its approval

in all patients

The manufacturer used two studies (P803 and P024) for the comparison of sitagliptin plus metformin with sulfonylurea plus metformin, both in the dossier on the free combination of sitagliptin (single agent) and metformin and in the dossier on the fixed combination.

Whereas a hint of an added benefit could be derived for sitagliptin in the free combination, the data were unsuitable for the fixed combination. The reason was that the approval stipulates a dose of at least 1700 mg metformin for the fixed combination. But patients who received a lower dose of metformin were also included in both studies. The number of these patients remained unclear.

Manufacturer subsequently submitted separate analyses according to dosage

In the commenting procedure, the manufacturer now presented subgroup analyses, which differentiated between patients with approval-compliant (at least 1700 mg) and lower dosage. These analyses showed that the study results did not depend on the metformin dosage, which means that the results of the two studies could also be used for assessing the fixed combination.

Hints of added benefit now also for the fixed combination

According to the results, there is a hint of a major added benefit – only in men, however – with regards to overall survival in comparison with the sulfonylurea glipizide plus metformin. There was a non-quantifiable added benefit due to fewer hypoglycaemias in women and men, but these results were only of limited robustness.

Compared with the sulfonylurea glimepiride, IQWiG sees a hint of a minor added benefit independent from the sex regarding hypoglycaemias – provided the treatment goal is near-normal levels of blood glucose.

Vildagliptin: Additional data did not change the result of the assessment

The manufacturer of vildagliptin as single agent and as fixed combination with metformin also submitted additional data in the commenting procedure. But they do not change the result of the dossier assessment dated July 2013: IQWiG does not see advantages neither of the single agent nor of the fixed combination in comparison with standard treatment.

G-BA decides on the extent of added benefit

The dossier assessment is part of the overall procedure for early benefit assessments supervised by the G-BA. After publication of the manufacturers' dossiers and the IQWiG dossier assessments, the G-BA conducted commenting procedures, in which the manufacturers submitted additional information. The G-BA subsequently commissioned IQWiG to assess the data subsequently submitted.

If, in the course of the discussions on a commission of the G-BA, a need for further revision arises, IQWiG presents its report in the form of an addendum. The Institute sent the addenda on sitagliptin/metformin and on vildagliptin and vildagliptin/metformin to the contracting agency on 29 August 2013. The G-BA then decides on the extent of the added benefit in each case, thus completing the early benefit assessment.

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