Added benefit of saxagliptin as monotherapy is not proven

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The drug saxagliptin (trade name: Onglyza) has been approved also as monotherapy in Germany since July 2013 for certain adults with type 2 diabetes mellitus. It is an option when drug treatment is needed, but the drug metformin is not tolerated or cannot be used.

In an early benefit assessment pursuant to the Act on the Reform of the Market for Medicinal Products (AMNOG), the German Institute for Quality and Efficiency in Health Care (IQWiG) examined whether saxagliptin offers an added benefit over the current standard therapy. Such an added benefit cannot be derived from the dossier, however, as the manufacturer did not submit any suitable data.

G-BA specified sulfonylurea as appropriate comparator therapy

Saxagliptin in combination with other drugs has already been available in Germany since 2009 and was already assessed by IQWiG as part of the assessment of the established drug market. Since the middle of this year, it can also be used as monotherapy. However, the precondition is that the patient has metformin intolerance or contraindication.

The Federal Joint Committee (G-BA) specified a sulfonylurea (glibenclamide or glimepiride) as appropriate comparator therapy.

No studies for direct comparison

The drug manufacturer did not provide a direct comparative study in its

dossier. However, it did conduct a so-called simple adjusted indirect comparison. For this comparison, it used studies that tested saxagliptin or a sulfonylurea versus placebo. The two drugs can then be compared with each other indirectly using placebo as the common comparator. In principle, such an indirect comparison with the studies described can be suitable to prove an added benefit.

Relevant patient group was not studied

However, this was not the case in the dossier on saxagliptin as monotherapy: In none of the eight studies in total, patients were investigated for whom metformin was not an option. Moreover, the duration in some of the studies was too short to draw conclusions on benefit. Finally, in two of the studies, sulfonylureas were not used in compliance with the approval.

No added benefit of saxagliptin could be derived from the dossier because no suitable data were available for a direct or an indirect comparison with sulfonylurea.

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 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.

An overview of the results of IQWiG's benefit assessment is given by a German-language executive summary. In addition, the website gesundheitsinformation.de, published by IQWiG, provides easily

understandable and brief German-language information on saxagliptin.

Provided by Institute for Quality and Efficiency in Health Care