Added benefit of sucroferric oxyhydroxide is not proven

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Sucroferric oxyhydroxide (trade name Velphoro) has been approved since August 2014 for adults with chronic kidney disease on haemodialysis or peritoneal dialysis. The German Institute for Quality and Efficiency in Health Care (IQWiG) examined in a dossier assessment whether in these cases the drug offers patients an added benefit over the appropriate comparator therapies. According to the findings, an added benefit is not proven because no suitable data were available.

G-BA specifies appropriate comparator therapy

If the kidney cannot regulate the salt, water and acid-base balance anymore, phosphate, among other substances, accumulates in the blood (hyperphosphataemia). Phosphate binders aim to help bind the phosphate ingested with the food before it enters the blood stream and reduce complications such as cardiovascular disease.

The Federal Joint Committee (G-BA) distinguished between patients with and without contraindication to calcium-based phosphate binders: If calcium-based phosphate binders are not an option, sucroferric oxyhydroxide was to be compared with sevelamer or lanthanum carbonate. If there is no contraindication, these two drugs as well as calcium-based phosphate binders are available as comparator therapy.

Drug was over- or underdosed in the studies

In one of the two studies presented (PA-CL-03A), the appropriate comparator therapy (sevelamer) was not used in compliance with the approval, and the starting dose was exceeded in more than half of the patients (approximately 64%). Furthermore, individual dose adjustment, as recommended by the approval, was not allowed in the sevelamer treatment or in the sucroferric oxyhydroxide treatment. It was also not ensured that additional calcium supplements, vitamin D3 derivatives or their analogues were given to control the development of renal bone disease. However, this is part of the multiple therapeutic approach, which should be applied when administering sucroferric oxyhydroxide according to the approval.

In the second study (PA-CL-05A/05B), the starting dose of both drugs was not in compliance with the approval. This resulted in an underdosing in all patients in the sucroferric oxyhydroxide arm, and in an overdosing in roughly half of the patients (approximately 51%) in the sevelamer arm. Hence none of the studies presented is suitable for assessing the added benefit of sucroferric oxyhydroxide versus the appropriate comparator therapy.

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 decides on the extent of the added benefit, thus completing the early benefit assessment.

More information: www.iqwig.de/download/A14-37_S … ertung-35a-