Lomitapide in hypercholesterolaemia: No hint of added benefit

September 17 2015

Lomitapide (trade name: Lojuxta) has been available since July 2013 as additional treatment for adults with homozygous familial hypercholesterolaemia in whom diet and other drugs do not sufficiently lower cholesterol levels. The German Institute for Quality and Efficiency in Health Care (IQWiG) examined in a dossier assessment whether this drug offers an added benefit over the appropriate comparator therapy. No such added benefit could be derived, however, because the dossier contained no suitable data.

Diet, medication and apheresis are standard treatment

Homozygous familial hypercholesterolaemia is a very rare congenital metabolic disorder, in which the blood contains too much low density lipoprotein (LDL) cholesterol. Standard treatment options include diet together with lipid-lowering drugs or - if this is no longer sufficient - LDL apheresis, a procedure similar to dialysis, in combination with drug treatment.

The Federal Joint Committee (G-BA) distinguished between several patient groups for this assessment. This differentiation was based on whether drug and dietary options have been exhausted and whether LDL apheresis is already being used.

Drug manufacturer presented neither direct nor

indirect comparison

However, the dossier contained no data that would be suitable for the assessment of the added benefit for any of these patient groups. The manufacturer neither used a study of direct comparison nor conducted an indirect comparison. Results from a before-after comparison used by the company to derive an added benefit were unsuitable: Not only are before-after comparisons of small informative value anyway, but the concrete procedure in this case was inadequate. Hence the dossier provided no hint of an added benefit of lomitapide.

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.

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 German-language information.

More information: www.iqwig.de/download/A15-23_L … ertung-35a-SGB-V.pdf

Provided by Institute for Quality and Efficiency in Health Care

https://medicalxpress.com/news/2015-09-lomitapide-hypercholesterolaemia-hint-added-benefit.html