Insulin degludec plus liraglutide: Again no hint of added benefit in type 2 diabetes

November 18 2015

The fixed combination of the two drugs insulin degludec and liraglutide (trade name: Xultophy) has been approved since June 2015 also in adults with type 2 diabetes mellitus when oral antidiabetics (OADs) combined with a GLP-1 receptor agonist do not provide adequate glycaemic control. The German Institute for Quality and Efficiency in Health Care (IQWiG) examined in a dossier assessment whether this fixed combination offers an added benefit over the appropriate comparator therapy (ACT).

The manufacturer presented no relevant data for the assessment of the added benefit of insulin degludec/liraglutide versus the ACT. Hence no added benefit can be derived from the dossier. The manufacturer itself also claimed no added benefit for this therapeutic indication of the fixed combination.

Human insulin and metformin as appropriate comparator therapy

The Federal Joint Committee (G-BA) specified metformin plus human insulin as ACT for the new therapeutic indication of insulin degludec/liraglutide when OADs combined with a GLP-1 receptor agonist do not provide adequate glycaemic control. For patients for whom metformin is unsuitable according to the Summary of Product Characteristics, human insulin alone constitutes the ACT.

No relevant studies identified

No relevant study was available for a direct comparison.

In its literature search on an indirect comparison, the manufacturer identified the randomized controlled trial (RCT) DUAL III, in which insulin degludec/liraglutide was compared with continued ongoing treatment with a GLP-1 receptor agonist. This study would be potentially suitable for an indirect comparison versus the ACT human insulin plus metformin. However, the manufacturer identified no suitable study on the ACT in its search.

No hint of an added benefit

The manufacturer dossier therefore provided no relevant data for the assessment, and hence no hint of an added benefit of insulin degludec/liraglutide in combination with OADs can be derived. However, the manufacturer itself also claimed no added benefit for this therapeutic indication.

This is already the second dossier assessment for a therapeutic indication of the fixed combination of insulin degludec/liraglutide in which no hint of an added benefit has been found (see also dossier assessment A15-15 from August 2015).

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.

More information: www.iqwig.de/download/A15-30_I … ertung-35a-SGB-V.pdf

Provided by Institute for Quality and Efficiency in Health Care

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