HAUTE AUTORITÉ DE SANTÉ

DIABETOLOGY
New indication
April 2017

BRIEF SUMMARY OF THE TRANSPARENCY COMMITTEE OPINION

XULTOPHY (insulin degludec/liraglutide), antidiabetic

Insufficient actual benefit in the treatment of patients with type 2 diabetes not sufficiently controlled by a GLP-1 analogue + oral antidiabetics

Main points

- XULTOPHY now has Marketing Authorisation in the treatment of adults with type 2 diabetes to improve glycaemic control in combination with oral antidiabetics when these, combined with a GLP-1 analogue, do not provide adequate glycaemic control.
- The fixed combination of a basal insulin, insulin degludec and GLP-1 analogue does not make it possible to adjust insulin doses to achieve glycaemic goals.
- XULTOPHY has no role in the therapeutic strategy in this indication.

Pre-existing indications*

- XULTOPHY already has Marketing Authorisation in the treatment of adults with type 2 diabetes to improve glycaemic control in combination with oral antidiabetics when these, alone or combined with a basal insulin, do not provide adequate glycaemic control.

Therapeutic use

- In case of failure of oral antidiabetics, insulin is the treatment of choice. GLP-1 analogues are reserved for specific clinical situations (BMI ≥ 30 kg/m² or weight gain or concerning hypoglycaemia with insulin).
- The combination of a GLP-1 agonist with basal insulin alone has no place in therapeutic use today.
- **Role of the proprietary medicinal product in the therapeutic strategy**

  XULTOPHY has no place in the therapeutic strategy of patients with type 2 diabetes not sufficiently controlled by a GLP-1 analogue + oral antidiabetics.

Clinical data

An open-label study (which limits its robustness) included patients who were not controlled by a GLP-1 analogue (mostly liraglutide or exenatide) combined with oral antidiabetics (metformin ± pioglitazone ± hypoglycaemic sulphamide). A total of 438 patients were randomised between one group with insulin degludec/liraglutide (with forced, individualised titration) combined with metformin ± pioglitazone ± hypoglycaemic sulphamide and another group with GLP-1 analogue combined with metformin ± pioglitazone ± hypoglycaemic sulphamide in which patients had to keep the dose and their treatment unchanged during the study period. After 26 weeks of treatment, the HbA1c had decreased on average by 1.3% to reach 6.4% in the insulin degludec/liraglutide group and 0.3% to reach 7.4% in the GLP-1 analogue group, with a statistically more significant difference in variation in HbA1c in the insulin degludec/liraglutide group than in the GLP-1 analogue group (estimated difference in variation: -0.94 95%CI [-1.11; -0.78], p<0.001) (primary endpoint).
There are no comparison studies of insulin degludec/liraglutide versus the administration of its two separate components, or any data on compliance.
The safety results of this study do not change the known safety profile of insulin degludec/liraglutide.

* This summary does not cover this indication.

Special prescribing conditions

- Initial prescription reserved for specialists in endocrinology, diabetes and metabolic disorders, or internal medicine.
- Unrestricted renewal.

Benefit of the medicinal product

- The actual benefit* of XULTOPHY is insufficient in the extension of the indication.
- Does not recommend inclusion on the list of reimbursable products for supply by pharmacists and for hospital use in the extension of the indication.

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This document was created on the basis of the Transparency Committee opinion of 5 april 2017 (CT-15551) and is available at **www.has-sante.fr**

* The actual benefit (AB) of a medicinal product describes its benefit primarily in terms of its clinical efficacy and the seriousness of the condition being treated. The HAS Transparency Committee assesses the AB, which can be substantial, moderate, low or insufficient for reimbursement for hospital use.