**BRIEF SUMMARY OF THE TRANSPARENCY COMMITTEE OPINION**

**VICTOZA** (liraglutide), antidiabetic

No clinical benefit demonstrated in the management of patients with type 2 diabetes in triple therapy

No role in the therapeutic strategy in dual therapy

**Main points**

- **VICTOZA** now has Marketing Authorisation in the treatment of type 2 (adult-onset) diabetes for the achievement of glycaemic control combined with basal insulin, with or without an oral antidiabetic, when these, combined with diet and exercise, do not provide adequate glycaemic control.

- Its efficacy has been demonstrated in placebo controlled study in triple therapy with basal insulin and metformin.

- Its use combined with basal insulin and metformin is restricted to patients with type 2 diabetes inadequately controlled by the combination of these two medicinal products and who are intolerant to or have a contraindication to the use of a sulfonylurea, or in whom triple therapy with insulin/metformin/sulfonylurea has failed.

**Pre-existing indication**

**VICTOZA** already has Marketing Authorisation for type 2 (adult-onset) diabetes to obtain glycaemic control in combination with oral antidiabetics.

This summary does not cover this indication

**Therapeutic use**

- Some patients do not achieve or maintain glycaemic targets with insulin therapy alone. It should therefore be combined with another antidiabetic. In practice, metformin is widely used in combination with insulin. In cases of contraindication or intolerance to metformin, sulfonylureas are offered.

- If the targets are not achieved with dual therapy, the doses of insulin can be increased, but this dose increase is often associated with an increased risk of hypoglycaemia and weight gain. Glenpir + insulin + metformin triple therapy is currently one therapeutic option for patients who do not achieve or maintain glycaemic targets under dual therapy with insulin and metformin. The same applies to novanox in triple therapy with metformin and insulin, as well as to SGLT2 cotransporter inhibitors (dapagliflozin, canagliflozin and empagliflozin).

- **Role of the medicinal product in the therapeutic strategy**

  In dual therapy with basal insulin:

  In view of the lack of clinical data for liraglutide in combination with basal insulin on its own, and because its use in this indication is not recommended, **VICTOZA** does not have a role in dual therapy with basal insulin.

  In triple therapy with basal insulin and metformin:

  **VICTOZA** is a treatment alternative to fast-acting insulin when initiating triple therapy comprising basal insulin and metformin at an optimal dose in patients with type 2 diabetes who are not adequately controlled by these medicinal products, who are intolerant to or have a contraindication to the use of a sulfonylurea, or in whom triple therapy with insulin/metformin/sulfonylurea has failed.

  This use is set down in a specialist opinion justifying the escalation of treatment for the management of type 2 diabetes.
Clinical data

- The superiority of liraglutide in combination with basal insulin (glargine or detemir) and metformin (93% of patients) has been demonstrated versus placebo in a randomised double-blind study that included 450 patients with a difference in the change in HbS1c (primary endpoint) at 26 weeks of -1.2% between the groups favouring liraglutide: reduction of HbA1c of -1.4% in the liraglutide group and -0.2% in the placebo group.
- The most commonly observed adverse events were of a gastrointestinal nature (particularly nausea and diarrhoea), which were more frequent under liraglutide than under placebo and insulin aspart. Episodes of hypoglycaemia were less common under liraglutide than under insulin aspart. The risk of pancreatitis has been the subject of special monitoring.

Benefit of the medicinal product

- The actual benefit* of VICTOZA, including in patients with mild or moderate renal impairment, is:
  - insufficient in dual therapy in combination with basal insulin,
  - substantial in triple therapy in combination with basal insulin and metformin in patients with type 2 diabetes inadequately controlled by these treatments, who are intolerant to or have a contraindication to the use of a sulfonylurea, or in whom triple therapy with insulin/metformin/sulfonylurea has failed.

- In triple therapy with basal insulin and metformin:
  Taking into account the demonstrated superiority of liraglutide in relation to placebo and its safety profile, in the absence of a comparison with an oral antidiabetic, and taking into account the methodological limitations of its comparison with insulin aspart, VICTOZA does not provide clinical added value** (CAV V) in combination with basal insulin and metformin in patients with type 2 diabetes inadequately controlled by these treatments, who are intolerant to or have a contraindication to the use of a sulfonylurea, or in whom triple therapy with insulin/metformin/sulfonylurea has failed.

- Recommends inclusion on the list of reimbursable products for supply by pharmacists and for hospital use.

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* The actual benefit (AB) of a proprietary 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.

** The clinical added value (CAV) describes the improvement in treatment provided by a medicinal product compared with existing treatments. The HAS Transparency Committee assesses the degree of CAV on a scale from I (major) to IV (minor). A level V CAV means “no clinical added value”.

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