HAUTE AUTORITÉ DE SANTÉ

GASTROENTEROLOGY
New medicinal product
December 2014

BRIEF SUMMARY OF THE TRANSPARENCY COMMITTEE OPINION

REVESTIVE (teduglutide), synthetic GLP-2 analogue

Moderate improvement in the treatment of patients with short bowel syndrome who have been receiving parenteral nutrition for several months.

Main points

- REVESTIVE has Marketing Authorisation in the treatment of short bowel syndrome in adults. Patients should be stable following a period of intestinal adaptation after surgery.
- Its efficacy versus placebo in reducing the volume of parenteral nutrition necessary was at least 20% after 24 weeks. The level of evidence of the demonstration of efficacy is low.
- Despite the lack of long-term efficacy and safety data and taking into account its efficacy in reducing the need for parenteral nutrition, in the absence of a therapeutic alternative, REVESTIVE provides a moderate therapeutic benefit in the treatment of short bowel syndrome in patients who have been receiving parenteral nutrition for several months.

Therapeutic use

- The management of short bowel syndrome as a cause of chronic intestinal failure is based on early initiation of parenteral nutrition in order to avoid malnutrition. Any prolonged period of parenteral nutrition exceeding three months must be managed by an accredited or specialist centre for home parenteral nutrition.
- Management also includes feeding and appropriate provision of fluids and electrolytes as well as the prevention of specific complications of short bowel syndrome.
- **Role of the medicinal product in the therapeutic strategy**
  REVESTIVE can be used in patients with short bowel syndrome, after a period of adaptation of 6 to 12 months receiving parenteral nutrition, when the adaptation options and compensatory hyperphagia do not permit withdrawal of parenteral nutrition.
  The Committee recommends that REVESTIVE is prescribed only by practitioners at accredited or specialist centres for parenteral nutrition and only after implementation of all the measures necessary to achieve withdrawal of parenteral nutrition.

Clinical data

- In a randomised double-blind study of 86 patients who had been receiving parenteral nutrition three times a week for at least one year, 63% of patients treated with teduglutide 0.05 mg/kg/day achieved at least a 20% reduction in the weekly volume of parenteral nutrition (primary endpoint) after 6 months of treatment compared with placebo (30.2%, p = 0.002).
- The most commonly reported adverse events were gastrointestinal disorders, disorders associated with fluid retention and erythema at the injection site.

Benefit of the medicinal product

- The actual benefit* of REVESTIVE is substantial in the treatment of patients with short bowel syndrome, after a period of adaptation of 6 to 12 months receiving parenteral nutrition, when the adaptation options and compensatory hyperphagia do not permit withdrawal of parenteral nutrition.
- REVESTIVE provides moderate clinical added value** (CAV III) in patients with short bowel syndrome who have been receiving parenteral nutrition for several months, when the adaptation options and compensatory hyperphagia do not permit withdrawal of parenteral nutrition.
- Recommends inclusion on the list of reimbursable products for supply by pharmacists and for hospital use.

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This document was created on the basis of the Transparency Committee Opinion of 03 December 2014 (CT-13835) and is available at **www.has-sante.fr**

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[i] * 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".