HAUTE AUTORITÉ DE SANTÉ

GASTROENTEROLOGY
New indication
March 2017

**BRIEF SUMMARY OF THE TRANSPARENCY COMMITTEE OPINION**

# REVESTIVE (teduglutide), synthetic GLP-2 analogue

**Moderate improvement in the treatment of children ≥ one year, and adolescents with short bowel syndrome who have been receiving parenteral nutrition for several months.**

## Main points

- REVESTIVE has now Marketing Authorisation in the treatment of short bowel syndrome in children ≥ one year and adolescents. Patients must be stable following a period of intestinal adaptation after surgery.
- A reduction in parenteral nutrition needs, allowing withdrawal for some patients, has been observed at 12 weeks. The level of evidence of the demonstration of efficacy is low.
- There are no long-term efficacy and safety data, but there is no therapeutic alternative, so the unmet medical need is substantial.

## Pre-existing indications*

- REVESTIVE already has Marketing Authorisation in the treatment of short bowel syndrome in adults.

## 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 dehydration and malnutrition. Any prolonged period of parenteral nutrition must be managed by an accredited centre for home parenteral nutrition in paediatrics.
- **Role of the proprietary medicinal product in the therapeutic strategy**
  REVESTIVE can be used in children with short bowel syndrome, after an adaptation phase lasting 6 to 12 months of parenteral nutrition and for whom adaptation possibilities have not enabled withdrawal from parenteral nutrition**.**
  It is recommended that prescriptions for REVESTIVE are initiated and renewed annually by practitioners at accredited centres for parenteral nutrition and only after all the necessary steps to withdraw the patient from parenteral nutrition have been taken.

## Clinical data

- A non-randomised, open-label study that included 42 patients aged 1 to 17 years with short bowel syndrome on stable parenteral nutrition showed a reduction of at least 20% in parenteral nutrition support at 12 weeks in 10 patients out of 14 treated with teduglutide 0.025 mg/kg/day and in 8 out of 15 treated with teduglutide 0.05 mg/kg/day. Four patients out of a total of 37 treated with teduglutide (10.8%) were weaned from parenteral nutrition at 12 weeks of treatment (end visit). After a 4-week withdrawal period, the parenteral nutrition was re-initiated in two of these patients.
- The safety profile of REVESTIVE in children and adolescents (aged 1 to 17 years) was comparable to that observed in adults: the most commonly reported adverse events were gastrointestinal disorders, disorders associated with fluid retention and erythema at the injection site.

* This summary of opinion does not cover these indications.

## Special prescribing conditions

- For hospital prescription.
- Prescription restricted to gastroenterology and hepatology specialists or doctors with nutrition training.
- Medicinal product requiring special monitoring during treatment.

## Benefit of the medicinal product

- The actual benefit* of REVESTIVE is substantial.
- REVESTIVE provides moderate clinical added value** (CAV III) in children from one year and in adolescents with short bowel syndrome who have been receiving parenteral nutrition for several months and for whom adaptation possibilities have not enabled withdrawal from parenteral nutrition**.**The Committee 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 08 March 2017 (CT-15797) 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.

** 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”.