

SUMMARY

teduglutide

REVESTIVE 1.25 and 5 mg

powder and solvent for solution for injection

Reassessment

Adopted by the Transparency Committee on 24 April 2024

Summary of opinion

Favourable opinion for maintenance of reimbursement in the treatment of adults with short bowel syndrome (SBS) following a period of intestinal adaptation of 6 to 12 months with parenteral nutrition (PN) when the adaptation options and compensatory hyperphagia do not permit withdrawal of parenteral nutrition.

Transparency Committee's conclusions

Clinical Benefit

- ➔ Short bowel syndrome (SBS) is a rare and serious disease, causing intestinal insufficiency that may be temporary or permanent and for which the supportive treatment is parenteral nutrition. The condition can be life-threatening due to mechanical, infectious or metabolic complications related to parenteral nutrition.
- ➔ This medicinal product is a curative background therapy for the chronic intestinal insufficiency associated with short bowel syndrome.
- ➔ The efficacy/adverse effects ratio remains high in adults.
- ➔ No other medicinal products have an MA in this indication (no alternative apart from surgery).
- ➔ REVESTIVE is a GLP-2 analogue that can be used in adults with short bowel syndrome (SBS) following a period of intestinal adaptation of 6 to 12 months with parenteral nutrition (PN) and when the adaptation options do not permit withdrawal of parenteral nutrition.

➔ Public health benefit

Considering:

- the seriousness of the disease, which can be life-threatening due to mechanical, infectious or metabolic complications related to parenteral nutrition,
- the low prevalence of the disease,
- the medical need partially met by parenteral nutrition and supportive care, and surgery,

- the partial response of REVESTIVE (teduglutide) to the identified need in terms of reduction in parenteral nutrition volume, permitting the withdrawal of parenteral nutrition in a few patients, and the absence of an established effect on morbidity and mortality,
- an additional impact in terms of quality of life in patients in whom parenteral nutrition has been withdrawn or those in whom the reduction in parenteral nutrition requirements enables the number of days of parenteral nutrition to be reduced (1 day on average) during treatment with teduglutide (REVESTIVE),
- the lack of any expected impact on the care and life pathway in the majority of patients,

REVESTIVE (teduglutide) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of REVESTIVE 1.25 mg and 5 mg (teduglutide) remains substantial in the MA indication.

The Committee issues a favourable opinion for maintenance of inclusion of REVESTIVE 1.25 mg and 5 mg (teduglutide) in both the list of covered drugs for outpatients and the list of covered drugs for inpatients approved for use in the indication and at the MA dosages.

Clinical Added Value

Considering:

- the efficacy results from new clinical studies, including some conducted in routine clinical practice in France, with a low level of evidence but consistent with the data previously assessed, with an efficacy of REVESTIVE (teduglutide) in terms of reduction in parenteral nutrition volume, making it possible to reduce parenteral nutrition by one day per week on average, and hence a benefit with regard to patients' quality of life,
- withdrawal of parenteral nutrition observed in a few patients treated with teduglutide,
- the absence of an established impact on morbidity and mortality,
- the safety profile of teduglutide (frequent but non-severe adverse effects) and the need to monitor patients treated with teduglutide (for endoscopic detection, of polyps in particular),

the Committee considers that REVESTIVE 1.25 mg and 5 mg (teduglutide) provides a minor clinical added value (level IV) in adult patients with short bowel syndrome (SBS) receiving parenteral nutrition (PN) for several months and when the adaptation and compensatory hyperphagia options do not permit withdrawal of parenteral nutrition.