Teduglutide (Revestive®) for the treatment of short bowel syndrome

Summary of recommendations by *Zorginstituut Nederland* (National Health Care Institute, the Netherlands) dated 31 July 2018.

Zorginstituut Nederland has carried out an assessment of the medicinal product teduglutide (Revestive®), whereby the following conclusion was reached.

In a letter dated 13 February 2018 (CIBG-18-05820), the Minister of Health, Welfare and Sport (VWS) asked *Zorginstituut Nederland* to carry out an assessment of teduglutide (Revestive®). This was in response to a request from the marketing authorisation holder to include this drug in the Medicine Reimbursement System (GVS).

The *Zorginstituut* has now completed its assessment, after being advised by the Scientific Advisory Board (WAR).

Results of the substantive assessment
Teduglutide is a glucagon-like peptide-2 (GLP-2)-analogue, produced by recombinant technology. Revestive® (powder for subcutaneous injection) is registered as an orphan drug for the treatment of patients aged 1 year and above with Short Bowel Syndrome (SBS). Patients should be stable following a period of intestinal adaptation after surgery. Due to their intestinal failure, these patients cannot cope with a normal diet and require parenteral nutrition.

Zorginstituut Nederland has concluded that for the treatment of short bowel syndrome with chronic type III intestinal failure, the therapeutic value of teduglutide is lower than that of placebo, when both are given in addition to best supportive care.

Although a reduction in parenteral support (at least 20% volume reduction) is measured in the group of teduglutide-users, patients remain dependent on a degree of parenteral nutrition. Furthermore, it is not clear to what extent the effects measured are the result of natural adaptation. No difference in quality of life can be demonstrated between the group treated with teduglutide and the control group.

Advice: do not include in the GVS
Based on the results of the assessment, *Zorginstituut Nederland* advises against including teduglutide (Revestive®) in the GVS.

Possible candidate for the conditional reimbursement program?
Since 1 January 2012, the Minister of Health, Welfare and Sport can decide to accept into the health care package – for a specific period – care that does not fulfil the (legal) definition of 'established medical science and medical practice'. This is on the condition that, within this period of conditional reimbursement, data are collected on the effectiveness and cost-effectiveness of the drug. Based on the collected data it is decided whether the drug can remain (without conditions) in the health care package.

Based on the criteria for the conditional reimbursement program – insofar as they can be assessed based on the currently available data –, we checked whether this

drug is a possible candidate for the program.[1]

Zorginstituut Nederland feels that teduglutide is not a candidate for the conditional reimbursement program because:

1) the manufacturer, the professional group and the patients' association have not substantiated the promising nature of the drug,
2) questions have been raised about the feasibility of any studies in the Netherlands,
3) studies are already taking place abroad, though it is not known whether these will give the results needed to evaluate whether the drug should be included in the health care package.

Zorginstituut Nederland does not rule out that, based on further insight, we could eventually reach a different conclusion on the promising nature of this drug. In that case, we will inform the Minister.

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The original text of this excerpt from advice of Zorginstituut Nederland was in Dutch. Although great care was taken in translating the text from Dutch to English, the translation may nevertheless have resulted in discrepancies. Rights may only be derived on the basis of the Dutch version of Zorginstituut Nederland's advice.
Furthermore, Zorginstituut Nederland points out that only the summary of this report was translated. A proper understanding of all relevant considerations and facts would require familiarity with the Dutch version of this report, including all appendices.

[1] The criteria can be found in the most recent version of the letter on procedures for the conditional inclusion of medical care. The letter can be found on our website www.zorginstituutnederland.nl.