Zorginstituut Nederland

Eltrombopag (Revolade®) in cases of severe aplastic anaemia

Summary of recommendations by Zorginstituut Nederland dated 22 February 2016, based on an evaluation by the WAR (Scientific Advisory Committee)

Zorginstituut Nederland has approved a pharmacotherapeutic report for the medicine eltrombopag (Revolade®) in cases of severe aplastic anaemia. They reached the following conclusion. Eltrombopag, together with best supportive care, has an added therapeutic value in comparison with best supportive care for patients with refractory aplastic anaemia who are not eligible for haematopoietic stem cell transplantation.

Medicine. **Eltrombopag (Revolade**®), 25, 50 and 75 mg film-coated tablets.

Background

In a letter dated 13 January 2016 (CIBG-16-1441), the Minister of VWS asked Zorginstituut Nederland to carry out a substantive assessment of eltrombopag (Revolade). The Zorginstituut, assisted by the Scientific Advisory Board (WAR), has now completed this assessment. Its considerations are specified in the pharmacotherapeutic report and the budget impact analysis. The manufacturer was exempted from performing a pharmaco-economic analysis.

Eltrombopag is available in the form of 25, 50 and 75 mg film-coated tablets. The product has already been included in the Medicines Reimbursement System (GVS) for the following indications: adult patients with chronic immune (idiopathic) thrombocytopenic purpura (ITP) and adult patients with a chronic infection with the hepatitis C virus (HCV), for the treatment of thrombocytopenia. List 2 conditions apply to these indications.

New registered indication

The current assessment relates to the manufacturer's request to extend the existing List 2 conditions for eltrombopag with the indication: Treatment of adult patients with acquired severe aplastic anaemia (SAA) who are refractory for previous immunosuppressive therapy or who underwent intensive prior treatment and are not eligible for haematopoietic stem cell transplantation.

Pharmacotherapeutic report

Eltrombopag, together with best supportive care, has an added therapeutic value in comparison with best supportive care for patients with refractory aplastic anaemia who are not eligible for haematopoietic stem cell transplantation.

Cost-consequence estimate

Taking into account a therapeutic added value, 100% market penetration after three years and 100% therapy compliance, extending the specific conditions of eltrombopag (Revolade) with severe aplastic anaemia would be accompanied by total costs at the expense of the pharmacy budget of about €1.7 million, up to a maximum of €2.1 million in 2018.

Furthermore, uncertainty exists about the number of patients with severe aplastic anaemia that will be eligible for treatment with eltrombopag. This is a maximum estimate, because the calculation is based on the assumption that no patients will be treated with stem cell transplantation.

Zorginstituut Nederlands's advice on inclusion in the GVS

Eltrombopag is already included on List 1B. Based on the above-mentioned considerations, we advise extending the List 2 conditions of eltrombopag and formulating as indicated below. Extending the specific conditions involves added costs.

Condition

1. exclusively for an insured person aged eighteen years and older with:
    a. acquired severe aplastic anaemia (SAA), who is refractory for previous immunosuppressive therapy, or who has undergone intensive pre-treatment and is not eligible for haematopoietic stem cell transplantation.

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*The original text of this excerpt from a **WAR-Report** 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 WAR-Report.*
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.