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Our reference
2021049169

Date 10 January 2022
Subject GVS advice on volanesorsen (Waylivra)

Dear Mr Blokhuis,

In your letter of 8 November 2021 (CIBG-21-02768), you asked the National Health Care Institute to assess whether the product volanesorsen (Waylivra®) is interchangeable with another product that is included in the Medicine Reimbursement System (GVS). The National Health Care Institute, advised by the Scientific Advisory Board (WAR), has completed this assessment. The considerations are included in the GVS report attached to this letter.

Volanesorsen (Waylivra®) is indicated as an adjunct to diet in adult patients with genetically confirmed familial chylomicronaemia syndrome (FCS) and at high risk for pancreatitis, in whom response to diet and triglyceride-lowering treatment has been inadequate. Volanesorsen is available as a pre-filled syringe containing 300 mg volanesorsen sodium corresponding to 285 mg volanesorsen in 1.5 ml of solution. The recommended starting dose of volanesorsen is 285 mg injected subcutaneously once a week for three months. After those three months, the dose frequency should be reduced to 285 mg every two weeks.

The market authorisation holder is asking for inclusion on List 1B of the Health Insurance Regulation.

Review of interchangeability
To determine the place of a medicinal product in the GVS, the product's interchangeability with medicinal products already included in the GVS must first be assessed. Volanesorsen (Waylivra®) is not interchangeable with any products in the GVS.

Therapeutic value
The National Health Care Institute has reached the final conclusion that volanesorsen (Waylivra®) as an adjunct to diet in adult patients with genetically confirmed FCS and at high risk for pancreatitis and in whom response to diet and triglyceride-lowering treatment has been inadequate, has added therapeutic value compared to the best supportive care.

Budget impact analysis
Treatment with volanesorsen costs €358,400 per patient in the first year of treatment and €291,200 per patient in the years thereafter. Taking account of assumptions about patient numbers, market penetration and treatment duration, the expected budgetary impact of volanesorsen is €2.7 to €4.0 million in the third year after inclusion in the package.

Pharmacoeconomic analysis
Based on the estimated budget impact, the product is exempt from pharmacoeconomic analysis. That is largely because of the very limited number of patients. At the same time, the National Health Care Institute notes that the annually recurring costs per patient are high. This is therefore certainly a case to bear in mind when evaluating the criteria for conducting a pharmacoeconomic analysis in future.

Advice
Based on the above considerations, the National Health Care Institute advises that you include volanesorsen (Waylivra®) on List 1B.

If the application of volanesorsen (Waylivra®) is included in the package, the National Health Care Institute recommends the following reimbursement conditions:

Conditions for volanesorsen (Waylivra®):
Only for insured persons aged 18 or older, as an adjunct to the diet for treating genetically confirmed familial chylomicronaemia syndrome (FCS) at high risk of pancreatitis in whom response to diet and triglyceride-lowering treatment has been inadequate.

Yours sincerely,

Sjaak Wijma
Chair of the Executive Board

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