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Contact
Ms M.J.S. de Vries

2022048181

Date 6 December 2022
Subject GVS advice fostamatinib (Tavlesse®)

Our reference
2022048181

Dear Mr Kuipers,

In your letter of 31 October 2022 (CIBG-22-04609), you asked the National Health Care Institute to assess whether the medicinal product fostamatinib (Tavlesse®) 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 now completed this assessment.

Fostamatinib is registered for the treatment of chronic immune thrombocytopenia (ITP) in adult patients who are refractory to other treatments.

The National Health Care Institute advises you to include fostamatinib in the GVS. The considerations are included in the GVS report attached to this letter.

Background
Fostamatinib is available as a 100 mg film-coated tablet containing 126.2 mg of fostamatinib disodium hexahydrate. The recommended initial dose of fostamatinib is 100 mg twice daily. The dose can be increased to a maximum dose of 150 mg twice daily.

The marketing authorisation holder is asking that the registered indication be included on List 1B of the Health Insurance Regulations.

Assessment 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. Fostamatinib is not interchangeable with any products in the GVS.

Assessment of therapeutic value
The National Health Care Institute concludes that fostamatinib complies with established medical science and medical practice for adult patients with chronic immune-mediated thrombocytopenia that are refractory to earlier treatments, including rituximab or thrombopoietin receptor antagonists (TPO-RAs) such as avatrombopag and eltrombopag. Based on the data, the National Health Care Institute concludes that fostamatinib for adult patients with chronic ITP who are

refractory to other treatments has an added therapeutic value as a third-line treatment compared to the current standard treatment. The results of the clinical studies show that fostamatinib has a clinically relevant effect on the prevention of haemorrhage in patients with long-term ITP who have already tried several treatments. 44% of patients treated with fostamatinib achieved a lasting response after more than 28 months follow-up.

Budget impact analysis
The average cost for one year of treatment with fostamatinib is approximately €55,000. Taking into account the assumptions surrounding patient numbers, market penetration and patient compliance, the List 1B inclusion of fostamatinib for chronic ITP will be accompanied by additional costs charged to the pharmaceutical budget of approximately €6.1 million in the third year after market introduction.

Advice
The National Health Care Institute recommends including fostamatinib (Tavlesse®) in List 1B of the Health Insurance Regulation. Inclusion in List 1B will lead to additional costs.

Yours sincerely,

Sjaak Wijma
Chairperson of the Executive Board