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Our reference
2021016998

Date 8 June 2021
Subject GVS advice Vocabria® and Rekambys®

Dear Ms van Ark,

In your letter of 9 February 2021 (CIBG-21-01418) you asked the National Health Care Institute to carry out a substantive assessment of whether the products Rekambys® (rilpivirine, prolonged-release suspension for injection) and Vocabria® (cabotegravir; 30mg film-coated tablet and prolonged-release suspension for injection) can be included in the Medicine Reimbursement System (GVS).

HIV-inhibiting medicinal products have held a special place in the GVS since the year 2000. On 30 March 2000, one of your predecessors stated that all antiretroviral drugs for the treatment of HIV infection are in principle eligible for inclusion in List 1B of the Health Insurance Regulation. These products do not require a pharmaco-economic evaluation. This means that an assessment of the interchangeability does not apply here.
As long as the Ministry maintains the separate reimbursement policy for HIV-inhibiting medicinal products, the National Health Care Institute will, where appropriate, prepare a summary report in the form of a letter report when assessing an HIV inhibitor for inclusion in the GVS (i.e. for placement on List 1B of the Health Insurance Regulation).

Substantive assessment
Appendix 3 contains background information on the assessment of the desirable and unintended effects of cabotegravir with rilpivirine, compared with the comparative treatments. The budget impact analysis is shown in Appendix 4.

Main results of the assessment
- The combination treatment with cabotegravir and rilpivirine is the first long-acting intramuscular antiretroviral (HIV-1) treatment. Cabotegravir with rilpivirine should be administered once every 2 months [intramuscular]. The marketing authorisation holder intends to market only the 3 ml injection of both substances in the Netherlands. The 2 ml injection (for monthly administration) will therefore not be available at this time.

- The National Health Care Institute has concluded that in the treatment of HIV-1 infection in adults whose infection is under control with other HIV

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medicines (HIV-1-RNA < 50 copies/ml), the combination of cabotegravir with rilpivirine (both via an intramuscular injection administered once a month or once every two months) has a therapeutically equal value compared to the continuation of the oral combination of antiretroviral treatment used.
- The marketing authorisation holder has indicated that they are submitting cabotegravir and rilpivirine at a price comparable to the current commonly used oral treatment combinations. However, taking into account the assumptions about the number of patients, a market penetration of 10% and a therapeutically equal value, inclusion of cabotegravir and rilpivirine on the GVS List 1B for HIV-1 infection in adults whose infection is under control, will mean additional costs charged to the pharmaceutical budget of approximately €981,000.
- It is important to mention that the injections will be given in the hospital in the first year, in order to be able to follow the effects and patient compliance of the injections properly. This could result in additional costs for the hospital budget. The marketing authorisation holder indicates that it is possible, after the first year, to determine the most suitable option for the patient, such as administration in the home situation. This would still involve additional care costs, which are outside the pharmaceutical budget.

Advice from the National Health Care Institute
Vocabria® (cabotegravir) and Rekambys® (rilpivirine) can be included in the GVS on List 1B of the Health Insurance Regulation.

Yours sincerely,

Sjaak Wijma
Chair of the Executive Board