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National Health Care Institute
Care
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Our reference
2021040973

Date 2 November 2021
Subject GVS report Lecigon®

Dear Mr Blokhuis,

In your letter of 18 May of this year (reference CIBG-21-01867), you asked the National Health Care Institute to assess whether levodopa/carbidopa/entacapon intestinal gel (Lecigon®) can be included in the Medicine Reimbursement System (GVS). The National Health Care Institute has now completed this assessment, by means of a marginal assessment. The considerations are included in the report attached to this letter.

Background
Lecigon® is registered for the treatment of advanced Parkinson's disease with severe motor fluctuations and hyperkinesia or dyskinesia when available oral combinations of Parkinson medicinal products have not given satisfactory results. It is available as an intestinal gel in a cartridge (=47 ml) containing 940 mg levodopa, 235 mg carbidopa monohydrate and 940 mg entacapone.
The total daily dose of Lecigon® is composed of three individually adjusted doses: the morning bolus dose, the continuous maintenance dose and extra bolus doses. The maximum recommended dosage per day is 100 ml (which corresponds to 2000 mg levodopa, 500 mg carbidopa monohydrate and 2000 mg entacapone).

Assessment of interchangeability
The fixed dose combination Lecigon® is not interchangeable with any products in the GVS.

Assessment of therapeutic value
No extensive clinical studies have been performed for the registration of Lecigon®, as it is another formulation of an already long-standing oral fixed dose combination. In addition, an intestinal gel with levodopa/carbidopa (Duodopa®) has already been registered. On the basis of the data, the National Health Care Institute concludes that levodopa/carbidopa/entacapon intestinal gel (Lecigon®) has an equal therapeutic value compared to levodopa/carbidopa intestinal gel (Duodopa®) and thus complies with the established medical science and medical practice.

Budget impact analysis

Based on a stable number of patients over the next three years, a market penetration and 100% substitution of Duodopa® by Lecigon®, the additional costs of Lecigon® are estimated at €6.2 to €14.7 million in the third year after inclusion in the package. To achieve a cost-neutral application of Lecigon®, the price of Lecigon® should be lowered by more than 17% at a dose reduction of 35%. With a dose reduction of 20%, the price would need to decrease by 33%. This would mean that a cassette of Lecigon® can cost no more than €54.61 to €67.21. The marketing authorisation holder informed us on 26 October that they are prepared to reduce the price by 17% and thus to a list price of €67.00 per cartridge.

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Advice

Lecigon® intestinal gel is not interchangeable with any other medicinal product in the GVS and is therefore in principle eligible for placement on List 1B. Now that there is equal therapeutic value and additional costs, we advise you, based on the above, to include Lecigon® intestinal gel in the GVS only if a price adjustment for the cartridge (max. €54.61 to €67.21) can ensure a cost-neutral application.

Yours sincerely,

Sjaak Wijma
Chair of the Executive Board