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Our reference
2021025349

Date 1 July 2021
Subject GVS assessment of calcifediol (Hidroferol®)

Dear Ms van Ark,

In your letter of 15 June (ref. CIBG-21-01970) you asked the National Health Care Institute to assess whether the medicinal product calcifediol (Hidroferol®) is interchangeable with a medicine already included in the Medicine Reimbursement System (the 'GVS' in Dutch). The National Health Care Institute has now completed this assessment. The considerations are included in the GVS report attached to this letter.

Background
Calcifediol is licensed for treating vitamin D deficiency in adults, in cases where the initial administration of high doses is required or where staggered administration over time is preferred, such as in the following situations:

- As an adjuvant for treating osteoporosis
- In patients with malabsorption syndrome
- Renal osteodystrophy
- Bone disorders induced by treatment with corticosteroid medicinal products.

The recommended dose is one capsule (0.266 mg calcifediol, equivalent to 15,960 IU vitamin D) once a month.

The manufacturer has applied for calcifediol to be included in List 1A in the 0A11CCBO V cluster, which already includes other vitamin D medicinal products for treating vitamin D deficiency.

Review of interchangeability
The National Health Care Institute carried out a marginal assessment. Based on the criteria for interchangeability, the National Health Care Institute has concluded that calcifediol (Hidroferol®) is interchangeable with the other medicinal products in the GVS cluster 0A11CCBO V, which includes various products containing colecalciferol.

Advice
Calcifediol (Hidroferol®) can be put in List 1A in the 0A11CCBO V cluster. The standard dose for calcifediol can be set at 8.7 micrograms.

Yours sincerely,

Tiana van Grinsven
Acting Chair of the Executive Board

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