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To the Minister of Medical Care and Sports  
PO Box 20350  
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2021024719

Date 21 July 2021  
Subject GVS advice on subcutaneous buprenorphine (Buvidal®)

**National Health Care  
Institute**

Care I

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**Our reference**

2021024719

Dear Ms van Ark,

In your letter of 16 March 2021 (CIBG-21-01601), you asked the National Health Care Institute to assess whether the product subcutaneous buprenorphine (Buvidal®) 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.

Subcutaneous buprenorphine (Buvidal®) is indicated for treating addiction to opioids, in the context of medical, social and psychological treatment. The treatment is intended for use in adults and young people aged 16 and above.

Subcutaneous buprenorphine is available as a solution for injection with delayed release. Each prefilled syringe contains 8, 16, 24, 32, 64, 96 or 128 mg buprenorphine. The recommended starting dose for subcutaneous buprenorphine is 16 mg with one or two additional doses of 8 mg at intervals of at least 1 day, up to a target dose of 24 mg or 32 mg during the first week of treatment. The recommended dose for the second week of treatment is the total dose administered during the starting week. Treatment with monthly subcutaneous buprenorphine may be commenced after starting treatment with weekly doses, in accordance with the dose conversion table in the Summary of Product Characteristics (SmPC) once the patient is stable on weekly treatment.

The marketing authorisation holder is asking for inclusion on List 1B of the Healthcare Insurance Regulations.

### **Review of interchangeability**

Oral methadone and sublingual buprenorphine + naloxone have been included in the GVS for treating opioid addiction. Methadone has been included in cluster 0N07BCAO V and sublingual buprenorphine + naloxone in cluster 0N07BCBO V.

In the GVS, the classification of medicinal products into groups of interchangeability distinguishes between, among other things, medicinal products administered through injection and non-injection medicinal products. For that reason, subcutaneous buprenorphine administered by injection is not interchangeable with oral methadone or sublingual buprenorphine + naloxone.

### **Therapeutic value**

The National Health Care Institute reached a final conclusion that subcutaneous buprenorphine meets the established medical science and medical practice for treating moderate to severe opioid addiction in adults aged 18 and older within the context of medical, social and psychological treatment and its therapeutic value is comparable with that of sublingual buprenorphine + naloxone.

### **Budget impact analysis**

The annual costs of subcutaneous buprenorphine are estimated at €4,510.56 per client. For sublingual buprenorphine + naloxone, the annual costs per client are €1,866.

Including subcutaneous buprenorphine for “treating addiction to opioids, in the context of medical, social and psychological treatment” is associated with additional costs chargeable to the pharmacy budget of between €0.9 and €2 million in the third year after inclusion in the basic health care package. Substitution costs have been taken into account; the costs in the third year without substitution are between €1.2 and €2.6 million.

### **Pharmacoeconomic analysis**

Based on the estimated budget impact, the product is exempt from pharmacoeconomic analysis.

The fact that an exemption for submitting a pharmacoeconomic evaluation has been granted does not mean that cost-effectiveness will no longer play a role in the final assessment<sup>1</sup>.

Given that subcutaneous buprenorphine is equally as effective as sublingual buprenorphine + naloxone but more expensive, it follows that subcutaneous buprenorphine is not cost-effective compared to sublingual buprenorphine + naloxone. After all, the difference in effectiveness is zero whereas the annual difference in costs is about €2,644.

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<sup>1</sup> Procedure for evaluating outpatient medicinal products, November 2018

**Advice**

The National Health Care Institute recommends that subcutaneous buprenorphine (Buvidal®) should be included in List 1B on the condition that there are no additional costs for the pharmacy budget.

Yours sincerely,

Sjaak Wijma  
*Chair of the Executive Board*

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