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To the Minister of Health, Welfare and Sport  
PO Box 20350  
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2023030599

Date 28 July 2023  
Re: GVS advice on subcutaneous glucagon (Ogluo®)

Dear Mr Kuipers,

In your letter of 1 May 2023 (CIBG-23-05421), you asked the National Health Care Institute to assess whether the medicinal product subcutaneous glucagon (Ogluo®) is interchangeable with another medicinal 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. The considerations are included in the GVS report attached to this letter.

Subcutaneous glucagon is indicated for the treatment of severe hypoglycaemia in adults, adolescents and children aged 2 and over with diabetes mellitus. It is available as a pre-filled pen for subcutaneous injection and contains a single dose of glucagon 0.5 mg or 1 mg. The recommended dose is 1 mg administered through subcutaneous injection.

#### **Assessment of interchangeability**

To determine the place of a medicinal product in the GVS, its interchangeability with other medicinal products already included in the GVS must first be assessed.

The blood glucose-increasing medicinal products intramuscular (IM) glucagon (Glucagen®, Glucagen hypokit®) and glucagon nasal powder (Baqsimi®) are included in the GVS for the indication 'severe hypoglycaemia in diabetes mellitus'.

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 this reason, glucagon solution for injection in a pre-filled pen (Ogluo®) and glucagon nasal powder are by definition not interchangeable. Therefore, this review only investigated the interchangeability of subcutaneous glucagon (Ogluo®) and the intramuscular glucagon emergency kit.

Based on clinically relevant differences in properties compared to the intramuscular glucagon emergency kit, it has been concluded that glucagon solution for injection in a pre-filled pen (Ogluo®) cannot be placed on List 1A. Next, the National Health Care Institute assessed whether subcutaneous glucagon (Ogluo®) is eligible for inclusion on List 1B.

#### **National Health Care Institute**

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### **Therapeutic value**

In November 2020, the National Health Care Institute already concluded that glucagon nasal powder has a therapeutic added value compared to intramuscular glucagon for the above indication. There is a difference in ease of use between nasal and IM glucagon. The intramuscular dosage form is an important causal factor for the underuse of glucagon in practice (with regard to the number of preparation steps and controls to fill syringes before they can be administered and the stress of administering an IM injection in an emergency situation in the event of unconsciousness). The National Health Care Institute concluded that there is an added value for glucagon nasal powder because in acute situations its ease of use prevents underuse of intramuscular glucagon.

Subcutaneous glucagon contains the same active substance as glucagon nasal powder and glucagon emergency kit. In simulation studies with subcutaneous glucagon compared to IM glucagon emergency kit, it has been demonstrated that subcutaneous glucagon too was administered correctly much more frequently than IM glucagon emergency kit. A difference in ease of use is therefore concluded for glucagon nasal powder compared to the IM glucagon emergency kit. The therapeutic added value of subcutaneous glucagon (Ogluo®) is sufficiently substantiated because this product, like the nasal formulation, will result in a clinically relevant improvement in the treatment of severe hypoglycaemia in practice.

The National Health Care Institute has come to the conclusion that subcutaneous glucagon (Ogluo®) meets the established medical science and medical practice for severe hypoglycaemia. Based on the data, subcutaneous glucagon has an added value compared to IM glucagon emergency kit and a comparable therapeutic value with nasal glucagon.

### **Budget impact analysis**

Taking into account the various assumptions with regard to substitution and market penetration, the inclusion of subcutaneous glucagon for severe hypoglycaemia on List 1B of the GVS will be associated with additional costs of €125,223 in year 3. There is uncertainty about the market penetration of this medicinal product.

### **Pharmaco-economic analysis**

Based on the estimated budget impact, the product is exempt from a pharmaco-economic analysis.

### **Advice**

Based on the above considerations, the National Health Care Institute advises that you include subcutaneous glucagon (Ogluo®) on List 1B.

Yours sincerely,

Sjaak Wijma  
*Chairperson of the Executive Board*

**National Health Care  
Institute**  
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