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2020051258

Our reference
2020051258

Date 18 January 2021
Subject GVS assessment oxybutynin intravesical solution (Vesolox®)

Dear Ms van Ark,

In your letter of 10 November 2020 (CIBG-20-1121), you asked the National Health Care Institute to assess whether oxybutynin intravesical solution (Vesolox®) 1 mg/ml is interchangeable with a product that is included in the Medicine Reimbursement System (GVS). The National Health Care Institute will answer your question on the basis of a limited review. The considerations are included in the GVS report attached to this letter.

Vesolox® is available as a 10 ml prefilled syringe containing 1 mg/ml of oxybutynin hydrochloride. In addition, the solution contains the following adjuvant with known effect: sodium 3.53 mg/ml.

Vesolox® is indicated for the suppression of detrusor overactivity due to spinal cord injury or myelomeningocele (spina bifida) in children aged 6 years and older, and adults who empty their bladder through clean intermittent catheterization, which is not adequately treated with oral anticholinergics.

Conclusions of interchangeability
Oxybutynin intravesical solution (Vesolox®) is not interchangeable with any other medicinal product that is included in the GVS.

Conclusion regarding placement on List 1B
In 2016, the National Health Care Institute concluded that the pharmacy preparation oxybutynin bladder fluid in the treatment of neurogenic bladder can be considered rational pharmacotherapy when patients cannot be helped by other medicinal management or minimally invasive treatment. Oxybutynin bladder fluid is available in the Netherlands as a pharmacy preparation in potencies of 0.1 mg/ml in 50 ml, 0.2 mg/ml in 50 ml and 1 mg/ml in 10 ml.

Oxybutynin intravesical solution 1mg/ml (Vesolox®) is registered on the basis of well-established use. This means that the registration authority has assessed its effectiveness on the basis of intensive literature review and current European treatment guidelines. It is not necessary for the applicant to submit new clinical trials for well-established use assessments. If new clinical research is lacking, the registration authority will make the assessment based on the available scientific literature. The indication of Vesolox® is more limited than the indication for which the National Health Care Institute has designated oxybutynin bladder liquid as

rational pharmacotherapy.

On the basis of the above considerations, oxybutynin intravesical solution is in principle eligible for inclusion on List 1B.

Budget impact analysis
The National Health Care Institute estimates that this affects about 106 patients each year. Inclusion in the GVS is accompanied by additional costs. The total cost for Vesolox® is estimated at €1.9 million per year. When the substitution of the pharmacy preparation is taken into account, the annual additional costs will be €0.7 million.

Advice from National Health Care Institute
On the basis of the above considerations, the National Health Care Institute recommends that oxybutynin intravesical solution (Vesolox®) 1mg/ml be included in List 1B of the Health Insurance Regulation.

Inclusion in the GVS is accompanied by additional costs. The total costs for Vesolox® are estimated at €1.9 million per year. When the substitution of the pharmacy preparation is taken into account, the annual additional costs will be €0.7 million.

Yours sincerely,

Sjaak Wijma
Chair of the Executive Board

National Health Care Institute
Care I

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