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2024014914

Date 7 June 2024
Re: GVS advice for midazolam nasal spray (Nasolam®)

Our reference
2024014914

Dear Ms Dijkstra,

In your letter of 9 January 2024 (reference CIBG-24-06478), you asked the National Health Care Institute to carry out a substantive review of whether midazolam nasal spray (Nasolam®) is interchangeable with a product that is included in the Medicine Reimbursement System insurance package, and if not, to assess its therapeutic value. The National Health Care Institute has since completed this assessment through a marginal review. The considerations are included in the GVS report attached to this letter.

Midazolam nasal spray (Nasolam®) is a short-acting sleep inducing and anticonvulsant medicinal product registered for use in adults and children > 12 kg aged 2 years and older:

- for moderate sedation before and during diagnostic or therapeutic procedures with or without local anaesthesia;
- as a premedication before the introduction of anaesthesia.
- for the treatment of prolonged, acute, convulsive epileptic seizures

The first two indications of midazolam are intended for inpatient care and the use of midazolam for these indications only takes place in the hospital. For this reason, the manufacturer only applies for inclusion in the GVS on List 1B for the indication: treatment of prolonged, acute, convulsive epileptic seizures in adults and children > 12 kg aged 2 years and older.

General
Midazolam nasal spray (Nasolam®) (as hydrochloride) is available as nasal spray 2.5 mg/dose, 3.75 mg/dose and 5 mg/dose. The dose depends on the patient's age and body weight and ranges from 2.5 mg to 5 mg per day.

Outcomes of the assessment
Assessment of interchangeability
Based on the criteria for interchangeability, it can be concluded that midazolam nasal spray (Nasolam®) is not interchangeable with any other medicinal product in the GVS. Based on this, it cannot be placed on List 1A. Next, the National Health Care Institute assessed whether the medicinal product is eligible for inclusion on List 1B.

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Therapeutic value
At present, midazolam nasal spray is a pharmacy preparation that can be reimbursed.

There are no studies specifically researching Nasolam®. The therapeutic value assessment of midazolam nasal spray is based on studies that were also used in the GVS report for midazolam Xiromed® (oromucosal). Midazolam nasal spray is effective in stopping a prolonged acute convulsion. Based on the available data, an added value of midazolam nasal spray compared to oromucosal midazolam has not been demonstrated. This means that midazolam nasal spray meets the criteria of established medical science and medical practice.

Budget impact analysis (BIA)
Midazolam nasal spray (Nasolam®) substitutes the pharmacy preparation of midazolam nasal spray. The inclusion on list 1B of the GVS of Nasolam® for prolonged, acute, convulsive epileptic seizures in adults and children > 12 kg aged 2 years and older is expected to lead to additional costs from the pharmaceutical budget of €1.4 million in year 3. In particular, there is uncertainty about the number of users and healthcare prescriptions per year and the market penetration.

Advice
Based on the above considerations, midazolam nasal spray (Nasolam ®) is in principle eligible for inclusion on List 1B of the GVS. Inclusion is accompanied by additional costs from the pharmaceutical budget estimated at €1.4 million in year 3.

Should you need any further information, please do not hesitate to contact us.

Yours sincerely,

Sjaak Wijma
Chairperson of the Executive Board