Zorginstituut Nederland

National Health Care Institute
Research, Development and Medicinal Products
Medicinal Products Team

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To the Minister of Health, Welfare and Sport
P.O. Box 20350
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2026013772

Our reference
2026013772

Date 8 July 2026
Re: GVS advice adrenaline nasal spray (EURneffy®) for anaphylaxis

Dear Ms Hermans,

In your letter of 4 May 2026 (CIBG-26-09735) you asked the National Health Care Institute to assess the adrenaline nasal spray (EURneffy®) for inclusion in the health insurance package. We advise you to include the adrenaline nasal spray (EURneffy®) in the Medicine Reimbursement System (GVS).

Disorder
Anaphylaxis is a very severe acute allergic reaction in which the immune system responds violently to a specific substance. This can block breathing and circulation, making anaphylaxis life-threatening in some cases. Approximately 0.3% of the total population experiences anaphylaxis at some point in their lives. In this medical emergency, adrenaline should be administered as soon as possible. Patients at risk of anaphylaxis are therefore advised to carry an adrenaline autoinjector (AAI). The adrenaline nasal spray is an alternative to the AAI.

Registered indication
Adrenaline nasal spray (EURneffy®) is indicated for the emergency treatment of allergic reactions (anaphylaxis) caused by insect stings or bites, foods, medicines and other allergens, as well as idiopathic anaphylaxis or anaphylaxis caused by exertion. Treatment is indicated for adults and children aged 4 years and older with a body weight of 15 kg or more.
It is available as a 1 mg or 2 mg dose in a nasal spray, with 100 microlitres of solution per single-dose container.

Claim by the marketing authorisation holder (MAH)
Adrenaline nasal spray (EURneffy®) has an equivalent value for the registered indication compared to administration of adrenaline with an autoinjector.

The marketing authorisation holder therefore requests inclusion in List 1B of the Health Insurance Regulation for the registered indication.

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Advice

The National Health Care Institute advises you to include adrenaline nasal spray (EURneffy®) in List 1B of the Health Insurance Regulations. Adrenaline nasal spray has an equivalent value to the AAI and thus complies with the established medical science and medical practice (SWP). Based on this equivalent value, the price of the adrenaline nasal spray, adjusted for its shelf life, should not exceed the price of the AAI. Inclusion based on the list price would mean additional costs to the pharmacy budget that are estimated to be €0.6 million in year 3.

We have explained below how we reached this advice.

Substantive assessment

Assessment of interchangeability
Based on the criteria for interchangeability, the National Health Care Institute concluded that adrenaline nasal spray is *not* interchangeable with the AAI included in the GVS. Based on this, the adrenaline nasal spray cannot be placed on List 1A. Next, the National Health Care Institute assessed whether adrenaline nasal spray is eligible for inclusion in List 1B.

Therapeutic value
The National Health Care Institute concluded that the adrenaline nasal spray has an equivalent value to the AAI for the above indication.
There is no evidence of the effect of the adrenaline nasal spray on reducing anaphylactic symptoms. This evidence is also lacking for the AAI, which was approved based on a comparison of the pharmacokinetic data with the intra-muscular (IM) adrenaline injection. In practice adrenaline has proven itself to be the effective gold standard (well-established use) in the treatment of certain anaphylactic reactions. Patients can self-administer, or bystanders can administer it to the patient, using an AAI. The adrenaline nasal spray contains the same active substance, administered through the nose instead of subcutaneously. The effectiveness and safety of the adrenaline nasal spray compared to an AAI and adrenaline IM were investigated in a small-scale study (EPI-15) involving healthy volunteers. The results show that the pharmacokinetic profile of the nasal spray falls between that of an AAI and an adrenaline IM injection. Given these results and the fact that they contain the same active substance, the National Health Care Institute considers it sufficiently plausible that in practice there is no clinically relevant difference. In addition, the side effects of adrenaline administered by nasal spray and AAI are similar.

Budget impact analysis
The National Health Care Institute estimates that 11,047 patients per year will be treated with the adrenaline nasal spray for the above indication in year 3 after inclusion in the package.
The effective shelf life, i.e. the average shelf life at the time the patient receives the device, was used to calculate the total cost per patient per year. This is the shelf life given by the marketing authorisation holder minus the time between production and actual issue to the patient. This is relevant because this is a preventive medication that often remains unused and needs to be replaced due to an expired shelf life. Based on real-world data, the average effective shelf life of the AAI is 10 months. This real-world data also forms the basis for calculating the

effective shelf life of the adrenaline nasal spray. The effective shelf life of the AAI (10 months) plus a 6 months longer shelf life after production (30 for the nasal spray and 24 for the AAI) gives an effective shelf life of 16 months for the nasal spray. The total costs per patient per year for the adrenaline nasal spray amount to €140. The total costs per patient per year for the AAI amount to €89. This results in macro costs of €1.5 million in year 3. When substitution of the AAIs is also taken into account, the budget impact in year 3 will be €0.6 million.

The patient organisation and physicians' associations indicate that there is a need for an alternative form of adrenaline administration, particularly due to fear of needles. However, there is some uncertainty about market penetration. There is also uncertainty about the effective shelf life of the nasal spray. Adjusting the effective shelf life has a significant impact on the cost per patient per year and therefore on the budget impact.

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

Yours sincerely,

M.J. Janssen
Chairperson of the Executive Board

Appendices:
- Assessment of interchangeability
- Pharmacotherapeutic report
- Budget impact analysis

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