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Care
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Our reference
2023047942

Date 22 November 2023
Re: latanoprost/netarsudil (Roclanda ®)

Dear Mr Kuipers,

In your letter of 25 September 2023 (reference CIBG-23-06082), you asked the National Health Care Institute to carry out a substantive assessment of whether the medicinal product latanoprost/netarsudil (Roclanda ®) is interchangeable with a product that is included in the Medicine Reimbursement System (GVS), and if not, to assess its therapeutic value. The National Health Care Institute, advised by the Scientific Advisory Board (WAR), has completed this assessment. Concerned parties were also consulted. The considerations are set out in the attached reports.

Latanoprost/netarsudil is indicated for the reduction of elevated intraocular pressure (IOP) in adult patients with primary open-angle glaucoma (POAG) or ocular hypertension (OHT) for whom monotherapy with a prostaglandin or netarsudil provides insufficient IOP reduction.

The marketing authorisation holder is asking for the registered indication to be included on List 1B of the Health Insurance Regulation.
It is concluded that latanoprost/netarsudil meets the established medical science and medical practice and can be placed on List 1B. As latanoprost/netarsudil has a therapeutic equivalent, the (net) price of latanoprost/netarsudil should not exceed that of bimatoprost/timolol.

In this letter, I explain our findings and final conclusion.

Outcome of the substantive assessment
Assessment of interchangeability
To determine the place of a medicinal product in the GVS, its interchangeability with medicinal products already included in the GVS must first be assessed. Based on the criteria for interchangeability, latanoprost/netarsudil is not interchangeable with other medicinal products included in the GVS.

Therapeutic value
Glaucoma is an eye disease involving loss of retinal nerve fibres. This may result in loss of field of vision. The first choice of medical management in POAG and OHT

is monotherapy with a prostaglandin analogue. If the IOP does not decrease sufficiently with monotherapy, a combination therapy of two medicinal products from different groups can be applied. A fixed dose combination is preferable to two separate preparations. The fixed dose combination most commonly used at present is a combination of a prostaglandin analogue and a beta blocker.

In a prospective multicentre, double-blind, randomised, non-inferiority study (MERCURY-3), latanoprost/netarsudil and bimatoprost/timolol combination preparations were directly compared in patients with POAG or OHT.
Despite a number of uncertainties, it is evident that both latanoprost/netarsudil and bimatoprost/timolol eye drops are able to significantly reduce IOP by 36.7% and 38.6% respectively. The National Health Care Institute concludes that there are probably no clinically relevant differences in the effect on IOP between treatments with latanoprost/netarsudil and bimatoprost/timolol eye drops.

Treatment with latanoprost/netarsudil may be associated with a clinically relevant increase in the incidence of intervention-related severe adverse effects compared to bimatoprost/timolol eye drops. Latanoprost/netarsudil eye drops also result in a clinically relevant increase in the number of patients who discontinue treatment due to adverse effects (regardless of severity) compared to bimatoprost/timolol eye drops.

The National Health Care Institute concludes that latanoprost/netarsudil meets the established medical science and medical practice for primary open-angle glaucoma and ocular hypertension. Based on this data, the National Health Care Institute concludes that the medicinal product has an equal value to bimatoprost/timolol.

Budget impact analysis (BIA)
The National Health Care Institute estimates that the population eligible for a fixed dose combination consists of a total of 130,775 patients. The budget impact is estimated with a growth of 3.3% per year and a market penetration of 8% in year 1, 12% in year 2 and 20% in year 3. This results in 30,578 patients eligible for latanoprost/netarsudil at year 3. This involves substitution of other fixed dose combinations.

There are several fixes dose combinations of prostaglandin analogues and beta-blockers for OHT and POAG on the Dutch market. However, only bimatoprost/timolol has been shown to be equivalent to latanoprost/netarsudil in terms of effectiveness. That is why the National Health Care Institute is using the prices of bimatoprost/timolol in its calculations in this BIA. The average annual cost of fixed dose bimatoprost /timolol combinations is €179.63 per patient. The annual cost of latanoprost/netarsudil is also €179.63 per patient. The total costs of latanoprost/netarsudil in year 3, based on the above-mentioned patient numbers, are €5,436,976. The eye drops should, in principle, be used for the duration of a patient's life.

Taking into account the duration of treatment with a bottle of latanoprost/netarsudil and the assumed market penetration, inclusion on List 1B of latanoprost/netarsudil for OHT and POAG will not be accompanied by additional costs borne by the pharmaceutical budget, since the costs of latanoprost/netarsudil are equal to the average costs of bimatoprost/timolol. In

particular, there is uncertainty about market penetration.

Pharmaco-economic analysis
Given its equivalent value to bimatoprost/timolol, a pharmaco-economic analysis is not applicable and the (net) price of latanoprost/netarsudil should not be higher than that of bimatoprost/timolol.

Advice
On the basis of the considerations mentioned above, the National Health Care Institute recommends that latanoprost/netarsudil should be included on List 1B in the GVS.

Yours sincerely,

Sjaak Wijma
Chairperson of the Executive Board

Annexes:
GVS report
PT file
BIA

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