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Date 4 March 2020
Subject GVS assessment of hydroquinine (Inhibin®)

Our reference
2020017336

Dear Mr Bruins,

In your letter of 12 August 2019, you requested Zorginstituut Nederland to assess whether hydroquinine (Inhibin®) is interchangeable with any other product currently included in the medication reimbursement system (GVS). The Zorginstituut has completed its assessment. The considerations are included in the pharmaco-therapeutic report attached to this letter.

Hydroquinine is indicated for patients with nocturnal muscle cramps, if medicinal treatment is necessary. Hydroquinine is available as a 100 mg tablet. The recommended dosage is 2 coated tablets at dinner, followed by 1 coated tablet before bedtime, for 14 days. If the cramps return, hydroquinine can be prescribed again.

The marketing authorization holder requests inclusion of hydroquinine on List 1A of the Health Insurance Decision'.

Outcome of the substantive assessment
Therapeutic value conclusion
The attached pharmaco-therapeutic report shows no clinical relevant effect of hydroquinine treatment, compared to placebo. There is a risk that patients will use hydroquinine longer than the recommended maximum duration of 2 weeks. This results in additional health risks.

The Zorginstituut concluded, advised by its Scientific Advisory Board (WAR), that hydroquinine has no added value in the treatment of nocturnal muscle cramps (if medicinal treatment is necessary) and because of the possible toxicity, especially in prolonged use, Zorginstituut Nederland does not recommend the use of this product. Concluding hydroquinine has no added benefit ('a lower therapeutic value').
The available data, although sufficient for market registration, does not permit a positive assessment of inclusion in the insured package.

Context of the assessment
Since 1990, hydroquinine has been registered as a medicinal product only in the Netherlands.

The Dutch College of General Practitioners (NHG) states that treatment of nocturnal muscle cramps with hydroquinine has very limited effect and is not recommended. Treatment with hydroquinine should only be considered in men and non-pregnant women with persistent, severe symptoms associated with sleep problems (and related symptoms during the day).
The Zorginstituut has submitted the pharmaco-therapeutic draft report for consultation to various relevant parties. The Dutch College of General Practitioners (NHG), the Dutch Society of Neurology (NVN) and the Netherlands Patient Federation have indicated that they agree to the draft report or have no comments.
A negative assessment by the Zorginstituut does not mean that hydroquinine is not available to the patient. It is still available on prescription from the pharmacy, but will have to be paid for by the patients themselves. This medication has been paid by the patients themselves ever since it became available and has been available without prescription in the pharmacy. Since June 2018, hydroquinine has only been available on prescription, which means an increase in the price per prescription (handling costs).

Advice on inclusion in the GVS
On the basis of the considerations mentioned above, the Zorginstituut recommends that hydroquinine should not be included in the GVS.

Future developments
The Zorginstituut is of course prepared to reassess the package eligibility of hydroquinine when additional research data not previously assessed by the Zorginstituut lead to scientific publications.

Yours sincerely,

Sjaak Wijma
Chair of the Executive Board

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Date
4 March 2020

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