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Minister of Medical Care and Sports
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2021012851

Date 15 April 2021
Subject GVS advice crisaborole (Staquis®)

**National Health Care
Institute**

Care I

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Our reference

2021012851

Dear Ms van Ark,

In your letter of 7 July 2020 (CIBG-20-0673), you requested the National Health Care Institute to carry out a substantive review of whether crisaborole (Staquis®) is interchangeable with a product that is included in the Medicine Reimbursement System (GVS). The National Health Care Institute has now completed its substantive assessment. The considerations are included in the pharmacotherapeutic report attached to this letter.

Crisaborole (Staquis®) is indicated for the treatment of mild to moderate atopic dermatitis in adults and children over the age of 2 with $\leq 40\%$ of the body surface affected. One gram of ointment contains 20 mg of crisaborole. In addition, the ointment contains 90 mg/g of propylene glycol as an adjuvant. Crisaborole ointment should be applied twice daily to the affected skin.

The marketing authorisation holder is asking for crisaborole to be included in List 1A of the Health Insurance Regulation.

The outcome of the assessment

Therapeutic value conclusion

The National Health Care Institute has come to the final conclusion that there is insufficient evidence to determine the value of crisaborole in relation to pimecrolimus and tacrolimus. This should lead to the conclusion that crisaborole does not comply with the established medical science and medical practice for the treatment of atopic dermatitis.

Advice on inclusion in the GVS

On the basis of the considerations mentioned above, the National Health Care Institute recommends that crisaborole should not be included in the GVS.

Future developments

The National Health Care Institute is of course prepared to reconsider the package eligibility of crisaborole when additional research data not previously assessed by the National Health Care Institute leads to scientific publications.

Yours sincerely,

Sjaak Wijma
Chair of the Executive Board

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