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Minister of Health, Welfare and Sport
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2022043723

Date 10 November 2022
Subject GVS assessment sublingually administered house dust mite extract
300 IR HDM (Actair®)

**National Health Care
Institute**

Care
Medicinal Products

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Contact

Ms M.J.S. de Vries

Our reference

2022043723

Dear Mr Kuipers,

In your letter of 31 May 2022 (CIBG-22-03904), you asked the National Health Care Institute to assess whether the product sublingually administered house dust mite allergen extract 300 IR HDM (Actair®), hereafter abbreviated to 300 IR HDM, can be included in the Medicine Reimbursement System (GVS).

Background

300 IR HDM is indicated for adolescents (12-17 years) and adults for the treatment of moderate to severe house dust mite-induced allergic rhinitis or rhino conjunctivitis, diagnosed by clinical history and a positive house dust mite sensitisation test (skin prick test and/or specific IgE).

300 IR HDM is available as a sublingual tablet containing 300 IR standardised allergen extract of the house dust mites *Dermatophagoides pteronyssinus* and *Dermatophagoides farinae* in equal parts. The recommended dose is one oral tablet daily. A 100 IR HDM tablet is available for dose escalation at the start of treatment.

The marketing authorisation holder requests inclusion of 300 IR HDM on List 1A of the Health Insurance Regulation for the therapeutic indication in a new to be formed cluster with sublingually administered house dust mite extract 12 SQ-HDM (Acarizax®), hereafter abbreviated as 12 SQ-HDM.

Assessment of interchangeability

Based on the criteria for interchangeability, the National Health Care Institute has concluded that 300 IR HDM is interchangeable with 12 SQ-HDM, which is currently included on GVS List 1B.

Substantive assessment

The considerations contained in the pharmaco-therapeutic report show that the desirable and undesirable effects of 300 IR HDM and 12 SQ-HDM in the therapeutic indication are similar on the basis of an indirect comparison. However, both have added value only in patients who continue to have severe symptoms despite adequate (medical) management.

The Dutch physicians' association has indicated that at present, patients should only be treated with a sublingually administered house-dust mite extract if, despite adequate medical management, they still suffer from severe nasal blockages, sleep problems due to allergy, and/or serious impediment of their daily functioning. Based on the data, the administration of 300 IR HDM to the subgroup of patients with a high symptom score at the start of the treatment results in a clinically relevant effect. The National Health Care Institute therefore finds that both sublingually administered house dust mite extracts only meet the established medical science and medical practice in case of severe persistent house dust mite induced allergic rhinitis or rhino conjunctivitis despite adequate medical management.

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Advice

Sublingually administered house dust mite allergen extract 300 IR HDM (Actair®) can be placed on List 1A of the Health Insurance Regulation in a new to be formed cluster with 12 SQ-HDM (Acarizax®). The standard dose for 300 IR HDM can be set at 300 IR¹ per day and for 12 SQ-HDM at 12 SQ² per day.

In the context of appropriate care, the National Health Care Institute recommends that, in the light of the above, the following compensation conditions be included for both products in this cluster:

Condition for sublingually administered house dust mite extracts 300 IR HDM (Actair®) and 12 SQ-HDM (Acarizax®):

Only for insured persons 12 years and older with sustained house-dust mite induced allergic rhinitis or rhino conjunctivitis, diagnosed by clinical history and a positive house dust mite sensitisation test (skin prick test and/or specific IgE), despite adequate medical management.

Yours sincerely,

Sjaak Wijma
Chairperson of the Executive Board

¹ The IR unit is defined to measure the allergenicity of an allergen extract. The IR unit is not comparable to the units used by other allergen producers. Source: EMA. SmPC Actair®

² SQ is a standardisation method for the biological strength, amount of major allergen and complexity of allergen extract. Source: EMA. SmPC Acarizax®