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Marie Sherlock, T.D.
Dáil Éireann,
Leinster House,
Kildare Street,
Dublin 2.

10th October 2025

PQ: 51589/25

To ask the Minister for Health the arrangements that will be put in place for those who received the drug alcarizax through discretionary arrangements but cannot receive this due to a negative reimbursement decision, and who require completing this course of medication; and if she will make a statement on the matter. -Marie Sherlock

Dear Deputy Sherlock,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 51589/25), which you submitted to the Minister for Health for response.

There are formal processes which govern applications for the pricing and reimbursement of medicines, and new uses of existing medicines, to be funded and/or reimbursed.

The HSE considers the following criteria prior to making any decision on pricing/ reimbursement, in line with the Health (Pricing and Supply of Medical Goods) Act 2013:

- (1) The health needs of the public,
- (2) The cost effectiveness of meeting health needs by supplying the item concerned rather than providing other health services,
- (3) The availability and suitability of items for supply or reimbursement,
- (4) The proposed costs, benefits, and risks of the item or listed item relative to therapeutically similar items or listed items provided in other health service settings and the level of certainty in relation to the evidence of those costs, benefits and risks,
- (5) The potential or actual budget impact of the item or listed item,
- (6) The clinical need for the item or listed item,
- (7) The appropriate level of clinical supervision required in relation to the item to ensure patient safety,

- (8) The efficacy (performance in trial), effectiveness (performance in real situations) and added therapeutic benefit against existing standards of treatment (how much better it treats a condition than existing therapies) and,
- (9) The resources available to the HSE.

In this regard the terms of the specific details of the application for pricing and reimbursement of House Dust Mite Extract (Acarizax®):

NCPE HTA ID: 20015

The HSE received an application for pricing and reimbursement of Acarizax® on 12th March 2020 from ALK-Abelló (the applicant) for the treatment of adult patients (18-65 years) diagnosed by clinical history and a positive test of HDM sensitisation (skin prick test and/or specific IgE) with persistent moderate to severe house dust mite allergic rhinitis despite use of symptom-relieving medication.

The first step in the process is the submission of a Rapid Review dossier (a clinical and economic dossier) to the National Centre for Pharmacoeconomics (NCPE) for assessment. The HSE commissioned the Rapid Review process on the 12th March 2020.

The NCPE Rapid Review assessment report was received by the HSE on the 30th April 2020. The NCPE advised the HSE that a full health technology assessment (HTA) was recommended to assess the clinical effectiveness and cost effectiveness of Acarizax® compared with the current standard of care (<https://www.ncpe.ie/house-dust-mite-extract-acarizax-for-allergic-rhinitis-hta-id-20015/>)

The company has not submitted a HTA dossier to the NCPE; therefore the cost-effectiveness of the technology could not be proven.

NCPE HTA ID: 20016

The HSE received an application for pricing and reimbursement of Acarizax® on 12th March 2020 from ALK-Abelló (the applicant) for the treatment of adult patients (18-65 years) diagnosed by clinical history and a positive test of house dust mite sensitisation (skin prick test and/or specific IgE) with house dust mite allergic asthma not well controlled by inhaled corticosteroids and associated with mild to severe house dust mite allergic rhinitis.

The first step in the process is the submission of a Rapid Review dossier (a clinical and economic dossier) to the National Centre for Pharmacoeconomics (NCPE) for assessment. The HSE commissioned the Rapid Review process on the 12th March 2020.

The NCPE Rapid Review assessment report was received by the HSE on the 30th April 2020. The NCPE advised the HSE that a full health technology assessment (HTA) was recommended to assess the clinical effectiveness and cost effectiveness of Acarizax® compared with the current standard of care.

The HSE commissioned a full Health Technology Assessment (HTA) on the 7th May 2020 as per agreed processes.

The NCPE Health Technology Assessment Report was received by the HSE on the 24th February 2023. The NCPE recommended that Acarizax® not be considered for reimbursement, for this indication unless cost-

effectiveness can be improved relative to existing treatments (<https://www.ncpe.ie/house-dust-mite-extract-acarizax-for-allergic-asthma-hta-id-20016/>) .

The HSE Corporate Pharmaceutical Unit (CPU) is the interface between the HSE and the Pharmaceutical Industry in relation to medicine pricing and reimbursement applications. The HSE CPU has met with the applicant to discuss this application.

The Drugs Group is the national committee which the HSE has in place to make recommendations on the pricing and reimbursement of medicines. The membership of the HSE Drugs Group includes public interest members. The HSE Drugs Group considers all of the evidence and makes a recommendation to the HSE Senior Leadership Team. The totality of clinical and economic evidence for Acarizax® for the treatment of adult patients (18-65 years) diagnosed by clinical history and a positive test of house dust mite sensitisation (skin prick test and/or specific IgE) with house dust mite allergic asthma not well controlled by inhaled corticosteroids and associated with mild to severe house dust mite allergic rhinitis, was comprehensively and extensively reviewed by the Drugs Group at the October 2023 meeting. The Drugs Group unanimously were unable to support a positive recommendation for Acarizax® under the Community Drugs Schemes (<https://www.hse.ie/eng/about/who/cpu/drugs-group-minutes/hse-drugs-group-minutes-october-2023.pdf>).

The decision making authority in the HSE is the HSE Senior Leadership Team. The HSE Senior Leadership Team decides on the basis of all the demands it is faced with (across all services) whether it can fund a new medicine, or new use of an existing medicine, from the resources that have been provided to it in line with the Health (Pricing and Supply of Medical Goods) Act 2013. The HSE Senior Leadership Team supported the Drugs Group recommendation not to reimburse House Dust Mite Extract (Acarizax®) indicated for the treatment of adult patients (18-65 years) diagnosed by clinical history and a positive test of house dust mite sensitisation (skin prick test and/or specific IgE) with house dust mite allergic asthma not well controlled by inhaled corticosteroids and associated with mild to severe house dust mite allergic rhinitis.

The HSE CPU met with the applicant recently. ALK notified CPU at the meeting that they intended to submit a new pricing and reimbursement application for the allergic rhinitis indication to encompass the now licensed paediatric cohort. CPU await submission of same.

ALK have also advised that they do not intend on pursuing reimbursement of the allergic asthma indication at this time.

There is one National Application, Assessment and Decision Process within the HSE and this cannot be circumvented. Therefore Acarizax® cannot be approved under Discretionary Hardship Arrangements or any Community Drug Schemes in advance of the formal processes set down under the Health (Pricing and Supply of Medical Goods) Act 2013. This applies to all licensed medicines in Ireland.

Yours sincerely,

Suzanne Doyle
Primary Care Reimbursement Service

The Health Service Executive operates the General Medical Services Scheme, which includes Medical Cards and GP Visit Cards, under the Health Act 1970, as amended. It has established a dedicated contact service for members of the Oireachtas specifically for queries relating to the status of Medical Cards and GP Visit Cards applications, which the Deputy / Senator may wish to use for an earlier response. Tel: 01-8647180 / email: Oireachtas.pcrs@hse.ie