



Feidhmeannacht na Seirbhíse Sláinte, Seirbhís Aisíocaíochta Cúraim Phríomhúil
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Health Service Executive, Primary Care Reimbursement Service
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Aindrias Moynihan, T.D.
Dáil Éireann,
Leinster House,
Kildare Street,
Dublin 2.

23rd April 2024

PQ: 14085/24

To ask the Minister for Health the timeline for current and continued investigations on providing approval for a medication (details supplied) on the drugs payment scheme; and if he will make a statement on the matter.-Aindrias Moynihan

Details Supplied:

Veoza which is suitable for women with contraindication to HRT having had oestrogen positive breast cancer or ovarian cancer and that targets moderate to severe vasomotor symptoms. Rapid view has completed with recommendation for further investigations.

Dear Deputy Moynihan,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 14085/24), which you submitted to the Minister for Health for response.

The HSE is committed to providing access to as many medicines as possible, in as timely a fashion as possible, from the resources available (provided) to it.

The HSE robustly assesses applications for pricing and reimbursement to make sure that it can stretch available resources as far as possible and to deliver the best value in relation to each medicine and ultimately more medicines to Irish citizens and patients.

HSE decisions on which medicines are reimbursed by the taxpayer are made on objective, scientific and economic grounds.

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 terms of the specific details of the application for pricing and reimbursement of Fezolinetant (Veoza®):

The HSE received an application for pricing / reimbursement on the 8th February 2024 from Astellas (the applicant) for Fezolinetant (Veoza®) indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.

- 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 9th February 2024.
- The NCPE Rapid Review assessment report was received by the HSE on the 12th March 2024. The NCPE advised the HSE that a full Health Technology Assessment (HTA) was recommended to assess the clinical effectiveness and cost effectiveness of Fezolinetant (Veoza®) compared with the current standard of care.
- The HSE commissioned a full Health Technology Assessment (HTA) on the 8th April 2024 as per agreed processes.
- The NCPE publishes details of medicines where the HSE has commissioned a Rapid Review assessment and / or a full health technology assessment on their website. The website is updated at regular intervals and includes assessment outcomes and updates on reimbursement for each individual medicine and indication listed. Details of the assessment(s) of Fezolinetant (Veoza®) are available at <https://www.ncpe.ie/fezolinetant-veoza-hta-id-24005/>.
- 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 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 pharmacoeconomic report will be reviewed by the HSE Drugs Group along with the outputs of commercial negotiations, and any patient group submission(s) received. The HSE Drugs

Group will consider all of the evidence and make a recommendation to the HSE Executive Management Team.

- The decision making authority in the HSE is the HSE Executive Management Team. The HSE Executive Management 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 application remains under consideration with the HSE. The HSE cannot make any comment on possible outcomes from the ongoing process.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Suzanne Doyle', written over a thin horizontal line.

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