Feidhmeannacht na Seirbhíse Sláinte, Seirbhís Aisíocaíochta Cúraim Phríomhúil
Bealach amach 5, M50, An Bóthar Thuaidh, Fionnghlas
Baile Átha Cliath 11, D11 XKF3
Fón: (01) 864 7100 Facs: (01) 834 3589

Health Service Executive, Primary Care Reimbursement Service
Exit 5, M50, North Road, Finglas,
Dublin 11, D11 XKF3
Tel: (01) 864 7100 Fax: (01) 834 3589

Richard Boyd Barrett, T.D.
Dáil Éireann,
Leinster House,
Kildare Street,
Dublin 2.

30th July 2025

PQ: 40169/25

To ask the Minister for Health whether a prolonged release melatonin drug (Slenyto or a generic prolonged release melatonin drug) will be made available in Ireland and covered by the medical card. - Richard Boyd Barrett

Dear Deputy Barrett,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 40169/25), 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 prolonged-release melatonin (Slenyto®):

The HSE received a complete application for pricing and reimbursement on the 5th July 2022 from Flynn Pharma (the applicant) for prolonged-release melatonin (Slenyto®) for the treatment of insomnia in children and adolescents aged 2-18 with Autism Spectrum Disorder (ASD) and / or Smith-Magenis syndrome, where sleep hygiene measures have been insufficient:

- 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 5th July 2022.
- The NCPE Rapid Review assessment report was received by the HSE on the 9th August 2022. The NCPE advised the HSE that a full Health Technology Assessment (HTA) was recommended to assess the clinical effectiveness and cost effectiveness of prolonged-release melatonin (Slenyto®) compared with the current standard of care.
- The HSE commissioned a full HTA on the 31st August 2022 as per agreed processes.
- The NCPE publishes details of medicines where the HSE has commissioned a Rapid Review assessment and/or a full HTA 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 prolonged-release melatonin (Slenyto®) are available at: https://www.ncpe.ie/melatonin-slenyto-hta-id-22048/
- 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. Pharmacoeconomic reports are reviewed by the HSE Drugs Group along with the outputs of any commercial negotiations, and any patient group submission(s) received. The HSE Drugs Group considers all of the evidence and makes a recommendation to the HSE Senior Leadership Team.
- 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.

- To date Flynn Pharma has not submitted a HTA dossier to the NCPE for assessment.

As it currently stands a completed HTA is required to progress this application, as per the formal processes governing the pricing and reimbursement of medicines.

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