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Robert Troy, T.D.
Dáil Éireann,
Leinster House,
Kildare Street,
Dublin 2.

16th July 2024

PQ: 28063/24

To ask the Minister for Health if he will urgently expedite the approval of fenfluramine for the treatment of dravet syndrome (Fenflkuramine). -Robert Troy

Dear Deputy Troy,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 28063/24), 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 Fenfluramine (Fintepla®):

Dravet Syndrome

- The HSE received an application for pricing and reimbursement of Fenfluramine (Fintepla®) on the 28th July 2023 from UCB Pharma (the applicant) for the treatment of seizures associated with Dravet syndrome as an add-on therapy to other anti-epileptic medicines for patients two years of age and older.

- 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 31st July 2023.

- The NCPE Rapid Review assessment report was received by the HSE on the 7th September 2023. A full health technology assessment (HTA) was recommended to assess the clinical effectiveness and cost effectiveness of Fenfluramine (Fintepla®) compared with the current standard of care.

- The HSE commissioned a full Health Technology Assessment (HTA) on the 29th September 2023 as per agreed processes.

- The NCPE Health Technology Assessment Report was received by the HSE on the 3rd July 2024. The NCPE recommended that Fenfluramine (Fintepla®) be considered for reimbursement if cost-effectiveness can be improved relative to existing treatments. (https://www.ncpe.ie/fenfluramine-fintepla-for-dravet-syndrome-hta-id-23048/)

- 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 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.

The application remains under consideration with the HSE. The HSE cannot make any comment on possible outcomes from the ongoing process.

Yours sincerely,

Suzanne Doyle
Primary Care Eligibility & Reimbursement Service