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David Cullinane, T.D.
Dáil Éireann,
Leinster House,
Kildare Street,
Dublin 2.

7th May, 2021

PQ: 20340/21

To ask the Minister for Health the status of the medication epidiolex; when it will be approved for reimbursement; and if he will make a statement on the matter. -David Cullinane

Dear Deputy Cullinane,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 20340/21), 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 the pricing and reimbursement of Cannabidiol (Epidyolex®):

- The HSE received two applications for pricing / reimbursement of Cannabidiol (Epidyolex®) on the 5th February 2020 for use as:
  - Adjunctive therapy of seizures associated with Lennox-Gastaut Syndrome (LGS) in conjunction with Clobazam, for patients 2 years of age and older
  - Adjunctive therapy of seizures associated with Dravet Syndrome (DS) in conjunction with Clobazam, for patients 2 years of age and older

- The first step in the process is the submission of a rapid review dossier. The HSE commissioned the rapid review process for both indications on the 5th February 2020. Following receipt of the rapid review dossiers the National Centre for Pharmacoeconomics (NCPE) advised the HSE (11th March 2020) that a full Health Technology Assessment (HTA) was required for both indications

- The HSE commissioned a full Health Technology Assessment for each indication on the 16th March 2020 as per agreed processes

- The NCPE Health Technology Assessment (HTA) reports were received by the HSE on the 8th March 2021

- The NCPE recommended that Cannabidiol (Epidyolex®) for the adjunctive treatment of seizures associated with Lennox-Gastaut Syndrome (LGS) in conjunction with Clobazam for patients 2 years of age and older not be considered for reimbursement unless cost-effectiveness can be improved relative to existing treatments: http://www.ncpe.ie/wp-content/uploads/2020/03/Technical-Summary_Cannabidiol-for-LGS-HTA-ID-20005-Final-Report.pdf

- The NCPE recommended that Cannabidiol (Epidyolex®) for the adjunctive treatment of seizures associated with Dravet Syndrome (DS) in conjunction with Clobazam for patients 2 years of age and older not be considered for reimbursement unless cost-effectiveness can be improved relative to existing treatments: http://www.ncpe.ie/wp-content/uploads/2020/03/Technical-Summary_Cannabidiol-for-DS-HTA-ID-20004-Final-Report.pdf

- 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 CPU engaged in commercial negotiations with GW Pharma (the applicant) in April 2021 regarding both applications for Cannabidiol (Epidyolex®)

- 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 final HTA reports will be reviewed by the HSE Drugs Group along with the outputs of commercial negotiations, and any patient group submission(s) received during the HTA process. The HSE Drugs Group will consider all 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 uses 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 applications remain 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