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Michael Cahill, T.D.
Dáil Éireann,
Leinster House,
Kildare Street,
Dublin 2.

27th May 2025

PQ: 23673/25
To ask the Minister for Health if Pluvicto, the new, life-changing prostate cancer medication that has been approved by the European Medicines Agency, will be made available to all public patients at the earliest possible date; the estimated full year cost of providing this treatment; and if she will make a statement on the matter. -Michael Cahill

Dear Deputy Cahill,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 23673/25), 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 Lutetium (177Lu) vipivotide tetraxetan (Pluvicto®):

The HSE received a complete application for pricing and reimbursement on the 9th January 2023 from Advanced Accelerator Applications, a Novartis Company (the applicant) for Lutetium (177Lu) vipivotide tetraxetan (Pluvicto®) in combination with androgen deprivation therapy (ADT) with or without androgen receptor (AR) pathway inhibition indicated for the treatment of adult patients with progressive prostate specific membrane antigen (PSMA) positive metastatic castration-resistant prostate cancer (mCRPC) who have been treated with AR pathway inhibition and taxane based chemotherapy:

- 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 January 2023.

- The NCPE Rapid Review assessment report was received by the HSE on the 10th February 2023. The NCPE advised the HSE that a full Health Technology Assessment (HTA) was recommended to assess the clinical effectiveness and cost effectiveness of Lutetium (177Lu) vipivotide tetraxetan (Pluvicto®) compared with the current standard of care.

- The HSE commissioned a full HTA on the 1st March 2023 as per agreed processes.

- The NCPE Health Technology Assessment Report was received by the HSE on the 12th August 2024. The NCPE recommended that Lutetium (177Lu) vipivotide tetraxetan (Pluvicto®) not be considered for reimbursement. Lutetium (177Lu) vipivotide tetraxetan (Pluvicto®). HTA ID: 23002 | National Centre for Pharmacoeconomics

- 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 Lutetium (177Lu) vipivotide tetraxetan (Pluvicto®) in combination with androgen

deprivation therapy (ADT) with or without androgen receptor (AR) pathway inhibition indicated for the treatment of adult patients with progressive prostate specific membrane antigen (PSMA) positive metastatic castration-resistant prostate cancer (mCRPC) who have been treated with AR pathway inhibition and taxane based chemotherapy was comprehensively and extensively reviewed by the Drugs Group at the April 2025 meeting. The Drugs Group unanimously did not recommend favour of reimbursement of lutetium (177Lu) vipivotide tetraxetan (Pluvicto®) in combination with androgen deprivation therapy (ADT) with or without androgen receptor (AR) pathway inhibition indicated for the treatment of adult patients with progressive prostate specific membrane antigen (PSMA) positive metastatic castration-resistant prostate cancer (mCRPC) who have been treated with AR pathway inhibition and taxane based chemotherapy.

- 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 Drugs Group recommendation has been progressed to the HSE Senior Leadership Team.

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 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