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Róisín Shortall T.D.
Dáil Éireann,
Leinster House,
Kildare Street,
Dublin 2.

1st February 2023

PQ: 1334/23

To ask the Minister for Health the status of a breast cancer treatment [Abemaciclib (Verzenios®)] which is already licensed by the European Medicines Agency; if he expects this product to be reimbursed under the medicine access scheme; the timeline for a decision on same; and if he will make a statement on the matter. -Róisín Shortall

Dear Deputy Shortall,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 1334/23), 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 Abemaciclib (Verzenios®):

Advanced or Metastatic Breast Cancer

The HSE received an application for pricing / reimbursement for Abemaciclib (Verzenios®) on the 3rd July 2020 from Eli Lilly (the applicant) for the treatment of women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer in combination with an aromatase inhibitor or Fulvestrant as initial endocrine-based therapy, or in women who have received prior endocrine therapy.

- The first step in the process is the submission of a Rapid Review dossier (a clinical and economic dossier) to the National Centre for Phamacoeconomics (NCPE) for assessment. The HSE commissioned the Rapid Review process on the 6th July 2020.

- The NCPE Rapid Review assessment report was received by the HSE on the 27th August 2020. The NCPE advised the HSE that a full HTA was recommended to assess the clinical effectiveness and cost effectiveness of Abemaciclib (Verzenios®) compared with the current standard of care, on the basis of the proposed price relative to currently available therapies. (https://www.ncpe.ie/drugs/abemaciclib-verzenios-hta-id-20033/)

- The HSE commissioned a full Health Technology Assessment (HTA) on the 1st September 2020 as per agreed processes.

- To date a HTA submission has not been received by the NCPE

- Eli Lilly communicated to CPU in January 2022 that, at this point in time, they did not intend to progress their application for pricing and reimbursement for Abemaciclib (Verzenios®) for the treatment of women with hormone receptor (HR) positive, human epidermal growth factor receptor 2 (HER2) negative locally advanced or metastatic breast cancer in combination with an aromatase inhibitor or Fulvestrant as initial endocrine-based therapy, or in women who have received prior endocrine therapy.

Early Breast Cancer

The HSE received an application for pricing / reimbursement on the 11th April 2022 from Eli Lilly (the applicant) for a new indication for Abemaciclib (Verzenios®) in combination with endocrine therapy for the adjuvant treatment of adult patients with hormone receptor (HR)-

positive, human epidermal growth factor receptor 2 (HER2)-negative, node positive early breast cancer at high risk of recurrence.

- The first step in the process is the submission of a Rapid Review dossier (a clinical and economic dossier) to the National Centre for Phamacoeconomics (NCPE) for assessment. The HSE commissioned the Rapid Review process on the 11th April 2022.

- The NCPE Rapid Review assessment report was received by the HSE on the 6th May 2022. The NCPE have advised the HSE that a full HTA is recommended to assess the clinical effectiveness and cost effectiveness of Abemaciclib (Verzenios®) compared with the current standard of care. (https://www.ncpe.ie/drugs/abemaciclib-verzenios-for-adjuvant-hr-positive-her2-negative-node-positive-early-breast-cancer-hta-id-22020/)

- The HSE commissioned a full Health Technology Assessment on the 26th May 2022 as per agreed processes.

- 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 for the early breast cancer indication remains under consideration. The HSE cannot make any comment on possible outcomes from the ongoing process.

Yours sincerely,

Suzanne Doyle
Primary Care Eligibility & Reimbursement Service