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

8th February 2022

PQ: 3387/22

To ask the Minister for Health if the HSE has considered a recommendation from the National Centre for Pharmacoeconomics which states that venetoclax in combination with obinutuzumab should be considered for reimbursement for patients with previously untreated chronic lymphocytic leukaemia; 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 3387/22), 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 Venetoclax in combination with Obinuztuzumab:

The HSE received an application for pricing / reimbursement of Venetoclax (Venclyxto®) in combination with Obinutuzumab on the 6th October 2020 for the treatment of adult patients with previously untreated chronic lymphocytic leukaemia (CLL).

- The first step in the process is the submission of a rapid review dossier. The HSE commissioned the rapid review process on the 7th October 2020. Following receipt of a rapid review dossier, the National Centre for Pharmacoeconomics (NCPE) advised the HSE (22nd October 2020) that a full Health Technology Assessment (HTA) was recommended to assess the clinical effectiveness and cost effectiveness of Venetoclax in combination with Obinutuzumab compared with the current standard of care (https://www.ncpe.ie/drugs/venetoclax-venclyxto-in-combination-with-obinutuzumab-gazyvaro-hta-id-20046/)

- The HSE commissioned a full Health Technology Assessment on the 27th October 2020 as per agreed processes

- The NCPE Health Technology Assessment report (https://www.ncpe.ie/wp-content/uploads/2020/10/Web-summary-Venetoclax-20046.pdf) was received by the HSE on the 17th August 2021. The NCPE recommended that Venetoclax (Venclyxto®) in combination with Obinutuzumab be considered for reimbursement

- The HSE Corporate Pharmaceutical Unit (CPU) is the interface between the HSE and the Pharmaceutical Industry in relation to medicine pricing and reimbursement applications. CPU engaged in commercial negotiations with AbbVie in November 2021 regarding their application for Venetoclax (Venclyxto®) in combination with Obinutuzumab

- 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. Venetoclax (Venclyxto®) in combination with Obinutuzumab was considered by the Drugs Group in January 2022. The final HTA report was reviewed by the HSE Drugs Group, along with the outputs of commercial negotiations, and the patient group submission received during the HTA process. The HSE Drugs Group recommended in favour of reimbursement of Venetoclax (Venclyxto®) in combination with Obinutuzumab for the treatment of adult patients with previously untreated chronic lymphocytic leukaemia (CLL)

- 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 HSE EMT considered the recommendation of the Drugs Group in January 2022 and subsequently supported reimbursement of Venetoclax (Venclyxto®) in combination with Obinutuzumab for the treatment of adult patients with previously untreated chronic lymphocytic leukaemia (CLL)
- The necessary administrative processes required for formal reimbursement are currently underway and the HSE anticipates that Venetoclax (Venclyxto®) in combination with Obinutuzumab for the treatment of adult patients with previously untreated chronic lymphocytic leukaemia (CLL) will be approved for eligible patients in the near future

Yours sincerely,

Suzanne Doyle
Primary Care Eligibility & Reimbursement Service