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Pádraig O'Sullivan, T.D.
Dáil Éireann,
Leinster House,
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27th June 2024

PQ: 25807/24

To ask the Minister for Health further to Parliamentary Question No. 158 of 22 May 2024, when the HSE executive management team will be in a position to approve or make a decision on the reimbursement application for dostarlimab (jemperli) indicated as monotherapy for the treatment of adult patients with recurrent or advance endometrial cancer; and if he will make a statement on the matter. -Pádraig O'Sullivan

Dear Deputy O'Sullivan,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 25807/24), 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 Dostarlimab (Jemperli®):

The HSE received an application for pricing / reimbursement on the 22nd October 2021 from GSK (the applicant) for Dostarlimab (Jemperli®) as monotherapy for the treatment of adult patients with mismatch repair deficient (dMMR)/microsatellite instability-high (MSI-H) recurrent or advanced endometrial cancer that has progressed on or following prior treatment with a platinum-containing regimen.

- 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 26th October 2021.

- The NCPE Rapid Review assessment report was received by the HSE on the 30th November 2021. The NCPE advised the HSE that a full HTA was recommended to assess the clinical effectiveness and cost effectiveness of Dostarlimab (Jemperli®) compared with the current standard of care.

- The HSE commissioned a full Health Technology Assessment (HTA) on the 22nd December 2021 as per agreed processes.

- The NCPE Health Technology Assessment Report was received by the HSE on the 27th March 2023. The NCPE recommended that Dostarlimab (Jemperli®) not be considered for reimbursement unless cost-effectiveness can be improved relative to existing treatments. https://www.ncpe.ie/dostarlimab-jemperli-hta-id-21045/

- 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 HSE Drugs Group consider all of the evidence and make a recommendation to the HSE Executive Management Team. The published minutes of the HSE Drugs Group are available at https://www.hse.ie/eng/about/who/cpu/drugs-group-minutes/ . Dostarlimab (Jemperli®) was initially reviewed by the Drugs Group in August 2023. The HSE Drugs Group unanimously recommended in favour of reimbursement of Dostarlimab (Jemperli®) as monotherapy for the treatment of adult patients with mismatch repair deficient (dMMR)/microsatellite instability-high (MSI-H) recurrent or advanced endometrial cancer that has progressed on or following prior treatment

with a platinum-containing regimen subject to an improved commercial offering. Following subsequent review, the August 2023 recommendation was maintained by the Drugs Group.

- 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 Dostarlimab (Jemperli®) 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