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Denis Naughten, T.D.
Dáil Éireann,
Leinster House,
Kildare Street,
Dublin 2.

23rd October 2024

PQ: 40084/24

To ask the Minister for Health if he will make a drug (Nivolumab or Opdivo) available on the drugs payment scheme; the current status of the cancer treatment in the drug reimbursement process; and if he will make a statement on the matter. -Denis Naughten

Dear Deputy Naughten,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 40084/24), 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.

Nivolumab (Opdivo®) is licensed for a range of cancer indications. In terms of the specific details of the application for pricing and reimbursement of Nivolumab (Opdivo®):

The HSE received an application for pricing / reimbursement of a new indication for Nivolumab (Opdivo®) on the 29th October 2021 from BMS (the applicant) for Nivolumab (Opdivo®) in combination with fluoropyrimidine- and platinum-based combination chemotherapy for the first line treatment of adult patients with HER2 negative advanced or metastatic gastric, gastro oesophageal junction or oesophageal adenocarcinoma whose tumours express PD-L1 with a combined positive score (CPS) ≥5.

- 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 1st November 2021.

- The NCPE Rapid Review assessment report was received by the HSE on the 29th November 2021. The NCPE advised the HSE that a full Health Technology Assessment (HTA) was recommended to assess the clinical effectiveness and cost effectiveness of Nivolumab (Opdivo®) compared with the current standard of care.

- The HSE commissioned a full Health Technology Assessment (HTA) on the 7th December 2021 as per agreed processes.

- The NCPE Health Technology Assessment Report was received by the HSE on the 11th July 2023. The NCPE recommended that Nivolumab (Opdivo®) in combination with chemotherapy not be considered for reimbursement unless cost-effectiveness can be improved relative to existing treatments. https://www.ncpe.ie/nivolumab-opdivo-for-advanced-or-metastatic-gastric-gastro-oesophageal-junction-or-oesophageal-adenocarcinoma-1l-hta-id-21049/

- 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 Nivolumab (Opdivo®) in combination with fluoropyrimidine- and platinum-based

combination chemotherapy for the first line treatment of adult patients with HER2 negative advanced or metastatic gastric, gastro oesophageal junction or oesophageal adenocarcinoma whose tumours express PD-L1 with a combined positive score (CPS) ≥5 was comprehensively and extensively reviewed by the Drugs Group at the January 2024 meeting. The Drugs Group by majority did not recommend in favour of reimbursement of Nivolumab (Opdivo®) in this indication (https://www.hse.ie/eng/about/who/cpu/drugs-group-minutes/hse-drugs-group-minutes-january-2024.pdf).

- 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 HSE Senior Leadership Team supported the Drugs Group recommendation not to reimburse Nivolumab (Opdivo®) in combination with fluoropyrimidine- and platinum-based combination chemotherapy for the first line treatment of adult patients with HER2 negative advanced or metastatic gastric, gastro oesophageal junction or oesophageal adenocarcinoma whose tumours express PD-L1 with a combined positive score (CPS) ≥5.

The application remains under consideration. 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