Seirbhís Aisíoca Príomhchúraim
Bealach amach 5 an M50, Án Bóthar Thuaidh, Fionnghlas, Baile Átha Cliath 11, D11 XKF3
Guthán: 01 8647100

Primary Care Reimbursement Service
Exit 5, M50, North Road, Finglas, Dublin 11, D11 XKF3
Tel: 01- 8647100

Jennifer Whitmore, T.D.
Dáil Éireann,
Leinster House,
Kildare Street,
Dublin 2.

20th September 2022

PQ: 45266/22

To ask the Minister for Health the availability of the drug pembro; the reason that some health insurance companies do not cover the drug; the way that a patient can avail of it if their health provider does not cover payment of the drug; and if he will make a statement on the matter. -Jennifer Whitmore

Dear Deputy Whitmore,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 45266/22), which you submitted to the Minister for Health for response.

The HSE is committed to providing access to as many medicines as possible, across all therapeutic areas (cancer and non-cancer), 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.

- 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 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 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 NCPE pharmacoeconomic report(s) are reviewed by the HSE Drugs Group along with the outputs of commercial negotiations, and any patient group submission(s) received. The HSE Drugs Group considers the totality of the evidence and makes 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.

All patients entitled to receive treatment in public hospitals in Ireland are considered to be eligible for treatment with medicines which have been approved for reimbursement by the HSE for the relevant indication when administered in a publicly funded hospital. Medicines that are reimbursed under the Oncology Drug Management System have specific eligibility and exclusion criteria detailed in the National Cancer Control Programme (NCCP) national chemotherapy regimens here.

The accompanying table below details the licenced therapeutic indications for Pembrolizumab (Keytruda®) and their status at 19th September 2022 with regards to HSE pricing and reimbursement approval.

Pembrolizumab Indication (as per SmPC 15th September 2022)	**Status**
Monotherapy for the treatment of adults and adolescents aged 12 years and older with advanced (unresectable or metastatic) melanoma.	Reimbursed*
Monotherapy for the adjuvant treatment of adults and adolescents aged 12 years and older with Stage IIB, IIC or III melanoma [with	Reimbursed**

lymph node involvement] and who have undergone complete resection.	
Monotherapy for the first -line treatment of metastatic non-small cell lung carcinoma (NSCLC) in adults whose tumours express PD-L1 with ≥ 50% tumour proportion score (TPS) with no EGFR or ALK positive tumour mutations.	Reimbursed
In combination with Pemetrexed and platinum chemotherapy, for the first-line treatment of metastatic non-squamous NSCLC in adults whose tumours have no EGFR or ALK positive mutations.	Reimbursed
In combination with Carboplatin and either paclitaxel or nab-paclitaxel, for the first line treatment of metastatic squamous non-small cell lung cancer (NSCLC) in adults.	Reimbursed***
As monotherapy is indicated for the treatment of locally advanced or metastatic non-small cell lung carcinoma in adults whose tumours express PD-L1 with a ≥ 1% TPS and who have received at least one prior chemotherapy regimen. Patients with EGFR or ALK positive tumour mutations should also have received targeted therapy before receiving Pembrolizumab.	Not reimbursed (application withdrawn)
Monotherapy in adult and paediatric patients aged three years and older with relapsed or refractory classical Hodgkin lymphoma (cHL) who have failed autologous stem cell transplant (ASCT) or following at least two prior therapies when ASCT is not a treatment option.	Reimbursed
Monotherapy for the treatment of locally advanced or metastatic urothelial carcinoma in adults who have received prior platinum-containing chemotherapy.	Reimbursed
Monotherapy for the treatment of locally advanced or metastatic urothelial carcinoma in adults who are not eligible for cisplatin-containing chemotherapy and whose tumours express PD-L1 with a combined positive score (CPS)≥10.	Reimbursed
Monotherapy or in combination with platinum and 5-fluorouracil chemotherapy, for the first-line treatment of metastatic or unresectable recurrent head and neck squamous cell carcinoma in adults whose tumours express PD-L1 with a CPS≥1.	Reimbursed
Monotherapy for the treatment of recurrent or metastatic head and neck squamous cell carcinoma in adults whose tumours express PD-L1 with a ≥ 50% TPS and progressing on or after platinum-containing chemotherapy.	Not reimbursed (no pricing and reimbursement application received to date)
In combination with Axitinib for the first-line treatment of advanced renal cell carcinoma in adults.	Not reimbursed (under review)
In combination with Lenvatinib for the first-line treatment of advanced renal cell carcinoma in adults.	Not reimbursed (under review)
Monotherapy for the adjuvant treatment of adults with renal cell carcinoma at increased risk of recurrence following nephrectomy, or following nephrectomy and resection of metastatic lesions.	Not reimbursed (under review)
As monotherapy for adults with MSI-H or dMMR colorectal cancer in the following settings: - first-line treatment of metastatic colorectal cancer; - treatment of unresectable or metastatic colorectal cancer after previous fluoropyrimidine-based combination therapy.	Not reimbursed (under review)

As monotherapy for the treatment of the following MSI-H or dMMR tumours in adults with: - advanced or recurrent endometrial carcinoma, who have disease progression on or following prior treatment with a platinum-containing therapy in any setting and who are not candidates for curative surgery or radiation; - unresectable or metastatic gastric, small intestine, or biliary cancer, who have disease progression on or following at least one prior therapy.	Not reimbursed (no pricing and reimbursement application received to date)
In combination with platinum and fluoropyrimidine-based chemotherapy, for the first-line treatment of locally advanced unresectable or metastatic carcinoma of the oesophagus or HER-2 negative gastroesophageal junction adenocarcinoma, in adults whose tumours express PD-L1 with a CPS ≥ 10.	Not reimbursed (under review)
In combination with chemotherapy as neoadjuvant treatment, and then continued as monotherapy as adjuvant treatment after surgery, for the treatment of adults with locally advanced, or early-stage triple-negative breast cancer at high risk of recurrence.	Not reimbursed (under review)
In combination with chemotherapy for the treatment of locally recurrent unresectable or metastatic triple-negative breast cancer in adults whose tumours express PD-L1 with a CPS ≥ 10 and who have not received prior chemotherapy for metastatic disease.	Not reimbursed (under review)
In combination with Lenvatinib for the treatment of advanced or recurrent endometrial carcinoma in adults who have disease progression on or following prior treatment with a platinum-containing therapy in any setting and who are not candidates for curative surgery or radiation.	Not reimbursed (under review)
In combination with chemotherapy with or without Bevacizumab for the treatment of persistent, recurrent, or metastatic cervical cancer in adults whose tumours express PD-L1 with a CPS ≥ 1.	Under review

*adults only (no P&R application for adolescents aged 12 years or older)
** application for adults and adolescent (≥12 years) with stage IIB or IIC melanoma following complete resection in process
*** restricted combination of Carboplatin + Paclitaxel

The HSE cannot comment on the business decisions taken by the private health insurers with regard to the medicines covered under their schemes.

Yours sincerely,

Suzanne Doyle
Primary Care Eligibility & Reimbursement Service