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22nd July 2024

PQ 30121/24: **To ask the Minister for Health the status of the reimbursement of radioligand therapy (RLT) treatments by the HSE; if he will ensure that this treatment is made available to cancer patients immediately once reimbursed; if he is aware that cancer patients were left waiting at least two years to receive one form of RLT after the treatment was reimbursed in 2021 due to the fact that the health service was not equipped to administer the treatment.**

Dear Deputy Lahart,

Lutetium (177Lu) oxodotreotide (Lutathera®) is licensed by the European Medicines Agency (EMA) and reimbursed by the HSE for the following indication:

- Treatment of unresectable or metastatic, progressive, well differentiated (G1 and G2), somatostatin receptor positive- gastroenteropancreatic neuroendocrine tumours (GEP- NETs) in adults.

Centralised funding can be claimed by publicly funded hospitals via the Oncology Drug Management Scheme (ODMS) where the requirements of the indication and the agreed eligibility criteria, as detailed in the NCCP national SACT regimen, are met.

To date there have been no additional treatment indications included in the EMA licence for Lutetium (177Lu) oxodotreotide (Lutathera®). This treatment and associated infrastructure to deliver treatment is available to eligible patients in St. Vincent's University Hospital (SVUH) and 13 patients have been treated as of June 2024 (self-reported by SVUH). As highlighted there was a delay in establishing the service at SVUH which was due to infrastructural requirements however all eligible patients were offered this treatment via the Treatment Abroad Scheme during this period.

Lutetium (177Lu) vipivotide tetraxetan (Pluvicto®) is licensed by the European Medicines Agency (EMA) for the following indication:

- In combination with androgen deprivation therapy (ADT) with or without androgen receptor (AR) pathway inhibition for the treatment of adult patients with progressive prostate specific

membrane antigen (PSMA) positive metastatic castration resistant prostate cancer (mCRPC) who have been treated with AR pathway inhibition and taxane based chemotherapy.

The company, Novartis, have applied to the HSE for the reimbursement of Lutetium (177Lu) vipivotide tetraxetan (Pluvicto®) and this application is currently in the HSE assessment process. The HSE National Centre for Pharmacoeconomics (NCPE) conducts assessments of pharmaceutical products and publishes the outcomes of their assessments on their website which is updated regularly. A full Health Technology Assessment (HTA) was commissioned on the 1st March 2023. The application remains under consideration with the HSE. The HSE cannot make any comment on possible outcomes or timelines from the ongoing process.
Details of the assessment(s) of Lutetium (177Lu) vipivotide tetraxetan (Pluvicto®) are available at: https://www.ncpe.ie/lutetium-177lu-vipivotide-tetraxetan-pluvicto/

To note, 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.

In relation to the preparation for the establishment of Lutetium (177Lu) vipivotide tetraxetan (Pluvicto®) treatment in Ireland, the NCCP are engaging with the eight adult NCCP designated cancer centres and St. Luke's Radiation Oncology Network (SLRON). These engagements are to understand firstly, if the hospital intends to implement the service if the treatment gets reimbursed, the numbers of patients the hospital could accommodate and the service readiness including if the required infrastructure is in place to deliver this treatment in their hospitals.

Engagements and planning will continue in an effort to mitigate against delays to treatment availability if/when Lutetium (177Lu) vipivotide tetraxetan (Pluvicto®) treatment is reimbursed and available.

Yours sincerely,

Patricia Heckmann

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National Cancer Control Programme