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| **NCPE Assessment**  Lutetium (177Lu) vipivotide tetraxetan (Pluvicto®)  Plain English Summary  August, 2024 |

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| **Drug name:** | Lutetium (177Lu) vipivotide tetraxetan  (pronounced loo-tee-shee-um vye-PIV-oh-tide te-TRAX-e-tan) in combination with androgen deprivation therapy with or without androgen receptor pathway inhibition for the treatment of adult patients with progressive prostate-specific membrane antigen-positive metastatic castration-resistant prostate cancer who have been treated with androgen receptor pathway inhibition and taxane-based chemotherapy |
| **Brand name:** | Pluvicto® |
| **HTA ID:** | 23002 |

**What is the NCPE?**

The National Centre for Pharmacoeconomics (NCPE) is a team of experts who look at the health benefits and costs of medicines. The HSE asks us to advise on whether or not a new medicine is good value for money. We give unbiased advice to help the HSE provide the most effective, safe and cost-effective (value for money) treatments for patients.

**How do we make our recommendations?**

Our main focus is on the health benefits and cost effectiveness of a medicine. We look at the wider costs and health benefits associated with a new medicine, for example:

* Does the new medicine work better than other treatments available in Ireland?
* Is the new medicine easier to give or easier to take compared with other treatments available in Ireland?
* Does the new medicine reduce the need for patients to be hospitalised?
* Does the new medicine improve the quality of a patient’s life over other treatments available in Ireland?
* Will the new medicine save resources elsewhere within the health system?

We review the information from clinical trials along with the cost and value for money data presented by the pharmaceutical company. We ask doctors and other healthcare professionals for advice about any health benefits of the new medicine compared with current treatments. We also ask patient organisations to send us their views on how the new drug may improve patients’ day-to-day experience of living with a disease.

**What is Pluvicto® used for?**

Pluvicto® is a radiopharmaceutical (a medicine that gives off a small amount of radioactivity) that contains the active substance lutetium (177Lu) vipivotide tetraxetan.

Pluvicto® is used to treat prostate cancer. It is used when the cancer is metastatic (spreading to other parts of the body), progressive, castration-resistant (worsens despite treatment to lower testosterone levels), and the cancer cells have a protein called prostate-specific membrane antigen (PSMA) on their surface (i.e. PSMA-positive prostate cancer). Pluvicto® is used together with androgen deprivation therapy in adults previously treated with androgen receptor pathway inhibitors (medicines for prostate cancer), and a taxane (a medicine for cancer). Androgen receptor pathway inhibitors may also be given with Pluvicto® and androgen deprivation therapy.

**What recommendation has the NCPE made to the HSE?**

We have recommended that the HSE should consider not funding Pluvicto. The HSE will consider our recommendation and make the final decision about reimbursement (funding). When making the funding decision, the HSE will also consider the additional [criteria](http://www.irishstatutebook.ie/eli/2013/act/14/schedule/3/enacted/en/html) outlined in the Health (Pricing and Supply of Medical Goods) Act 2013.

We have received a Patient Organisation Submission from Men Against Cancer (MAC) about Pluvicto® and shared it with the HSE. This submission will form part of the data that the HSE considers.

**Why did we make this recommendation?**

We have completed a full health technology assessment for this medicine. We recommend that the HSE consider not providing this medicine. This is because we did not receive enough information to clearly assess how well the medicine works compared with other ways of managing this condition. The price of the medicine is too high compared with other ways to manage this condition, and we believe that the medicine is very poor value for money.

The HSE considers a number of factors along with our recommendation when deciding whether to provide this medicine. These factors are listed in the Health (Pricing and Supply of Medical Goods) Act 2013.

**Next steps**

When the HSE receives our recommendation, it will look at all the relevant data about Pluvicto®. The HSE makes the final decision on reimbursement.

**Where can I get more information?**

You can get more information about Pluvicto® from the following online options:

* the NCPE Technical Summary Document
* Pluvicto European Public Assessment Report (EPAR) –[Medicine overview](https://www.ema.europa.eu/en/medicines/human/EPAR/pluvicto)
* searching for Pluvicto on our website ([www.ncpe.ie)](http://www.ncpe.ie/);
* searching for Pluvicto on the European Medicines Agency (EMA) website ([www.ema.europa.eu)](http://www.ema.europa.eu/).

Please refer to the NCPE website for updated information on the reimbursement status of this medicine