NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Lutetium-177 vipivotide tetraxetan in combination for treating PSMA-positive hormone-sensitive metastatic prostate cancer ID6589

Draft scope

Draft remit/evaluation objective

To appraise the clinical and cost effectiveness of lutetium-177 vipivotide tetraxetan within its marketing authorisation for treating PSMA-positive hormone-sensitive metastatic prostate cancer.

Background

Prostate cancer is a condition in which tumours develop in the prostate, a gland in the male reproductive system. The exact cause is unknown but environmental and genetic factors are associated with an increased risk of developing prostate cancer. The description 'hormone-sensitive prostate cancer' refers to a population that includes people with prostate cancer who have not had androgen deprivation therapy, or whose disease is continuing to respond to androgen deprivation therapy.

The incidence of prostate cancer increases with age and is higher in people of black African-Caribbean family origin and people with a family history of the condition.[1] 58,137 people were diagnosed with prostate cancer in England during 2023.[2] In 2022, 12% of people diagnosed in England had metastatic disease, that is, disease has spread to other parts of the body (for example, the bones).[3]

Prostate cancers can highly express a transmembrane protein called prostate-specifc membrane antigen (PSMA). PSMA expression is further increased in poorly differentiated, metastatic, and hormone-refractory prostate cancers.[4]

For metastatic (or advanced) hormone-sensitive prostate cancer, NICE technology appraisal guidance (TA) 995 recommends relugolix as an alternative androgen deprivation therapy. Newer hormonal treatments, enzalutamide, apalutamide, darolutamide alone or darolutamide (with docetaxel) are also recommended as treatment options with androgen deprivation therapy in people with metastatic prostate cancer (NICE TA712, 741, 1109 and 903 respectively). However, apalutamide is only recommended if docetaxel is not suitable. Abiraterone (originator and generics) plus androgen deprivation therapy with prednisolone or prednisone is recommended for treating newly diagnosed high-risk hormone-sensitive metastatic prostate cancer (NICE TA110). Degarelix, a gonadotrophin-releasing hormone antagonist, is recommended for treating advanced hormone-dependent (hormone-sensitive) prostate cancer in people with spinal metastases (NICE TA404).

The technology

Lutetium-177 vipivotide tetraxetan (Pluvicto, Novartis Pharmaceuticals UK) in combination with androgen deprivation therapy (ADT) and androgen receptor-directed therapy (ARDT) does not currently have a marketing authorisation in the UK for treating PSMA-positive hormone-sensitive metastatic prostate cancer. It has been

studied in phase 3 clinical trials in combination with ADT and ARDT compared to ADT and ARDT alone.

Intervention(s)	Lutetium-177 vipivotide tetraxetan
Population(s)	Adults with prostate-speciifc membrane antigen (PSMA), hormone-sensitive metastatic prostate cancer
Subgroups	If the evidence allows, the following subgroups of people will be considered: • people with newly diagnosed metastatic prostate cancer • people with high-risk metastatic prostate cancer.
Comparators	Traditional standard of care treatments: • androgen deprivation therapy alone (including orchidectomy, luteinising hormone-releasing hormone agonist therapy or monotherapy with bicalutamide) • relugolix • docetaxel with androgen deprivation therapy Novel hormonal agents: • enzalutamide with androgen deprivation therapy • apalutamide with androgen deprivation therapy • darolutamide with docetaxel and androgen deprivation therapy • darolutamide with androgen deprivation therapy • abiraterone with androgen deprivation therapy (with prednisolone or prednisone)
Outcomes	The outcome measures to be considered include: • overall survival • progression-free survival • response rate • adverse effects of treatment • health-related quality of life.

Economic analysis	The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year. The reference case stipulates that the time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared. Costs will be considered from an NHS and Personal Social Services perspective. The availability of any commercial arrangements for the intervention, comparator or subsequent treatment technologies will be taken into account. The availability and cost of biosimilar and generic products should be taken into account. The use of lutetium-177 vipivotide tetraxetan is conditional on the presence of PSMA-positive prostate cancer. The economic modelling should include the costs associated with diagnostic testing for PSMA in people with prostate cancer would would not otherwise have been tested. A sensitivity analysis should be provided without the cost of the diagnostic test. See section 4.8 of the guidance development manual (available here: https://www.nice.org.uk/process/pmg36/chapter/introduction-to-health-technology-evaluation).
Other considerations	Guidance will only be issued in accordance with the marketing authorisation. Where the wording of the therapeutic indication does not include specific treatment combinations, guidance will be issued only in the context of the evidence that has underpinned the marketing authorisation granted by the regulator.
Related NICE recommendations	**Related technology appraisals:** Abiraterone for treating newly diagnosed high-risk hormone-sensitive metatstatic prostate cancer (2025). NICE Technology appraisal guidance [TA110] Darolutamide with androgen deprivation therapy for treating hormone-sensitive metastatic prostate cancer (2025). NICE Technology appraisal guidance [TA1109] Reglugolix for treating hormone-sensitive prostate cancer (2024). NICE Technology appraisal guidance [TA995] Darolutamide with androgen deprivation therapy and docetaxel for treating hormone-sensitive metastatic prostate cancer (2023). NICE Technology appraisal guidance [TA903] Apalutamide with androgen deprivation therapy for treating hormone-sensitive metatatic prostate cancer (2021). NICE Technology appraisal guidance [TA741]

	Enzalutamide for treating hormone-sensitive metastatic prostate cancer (2021). NICE Technology appraisal guidance [TA712] **Related technology appraisals in development:** Niraparib with abiraterone acetate and prednisone for treating hormone-sensitive metastatic prostate cancer. NICE Technology appraisal guidance [ID6595] Talazoparib with enzalutamide for untreated hormone-sensitive metastatic prostate cancer with a homologous recombination repair mutation. NICE Technology appraisal guidance [ID6460] **Related NICE guidelines:** Prostate cancer: diagnosis and management (2019). NICE guideline [NG131] Suspected cancer: recognition and referral (2015). NICE guideline [NG12] **Related NICE guidelines in development:** Prostate cancer: diagnosis and management (update). NICE guideline. Publication date to be confirmed. **Related quality standards:** Prostate cancer (2015). NICE quality standard [QS91]

Questions for consultation

Is hormone-sensitive metastatic prostate cancer in England routinely tested for PSMA expression?

Where do you consider lutetium-177 vipivotide tetraxetan will fit into the existing care pathway for PSMA-positive hormone-sensitive metastatic prostate cancer?

Please select from the following, will lutetium-177 vipivotide tetraxetan be:
A. Prescribed in primary care with routine follow-up in primary care
B. Prescribed in secondary care with routine follow-up in primary care
C. Prescribed in secondary care with routine follow-up in secondary care
D. Other (please give details):
For comparators and subsequent treatments, please detail if the setting for prescribing and routine follow-up differs from the intervention.

Would lutetium-177 vipivotide tetraxetan be a candidate for managed access?

Do you consider that the use of lutetium-177 vipivotide tetraxetan can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation?

Please identify the nature of the data which you understand to be available to enable the committee to take account of these benefits.

Please indicate if any of the treatments in the scope are used in NHS practice differently than advised in their Summary of Product Characteristics. For example, if the dose or dosing schedule for a treatment is different in clinical practice. If so,

please indicate the reasons for different usage of the treatment(s) in NHS practice. If stakeholders consider this a relevant issue, please provide references for data on the efficacy of any treatments in the pathway used differently than advised in the Summary of Product Characteristics.

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that the proposed remit and scope may need changing in order to meet these aims. In particular, please tell us if the proposed remit and scope:

- could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which lutetium-177 vipivotide tetraxetan will be licensed;

- could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the technology;

- could have any adverse impact on people with a particular disability or disabilities.

Please tell us what evidence should be obtained to enable the committee to identify and consider such impacts.

NICE intends to evaluate this technology through its Single Technology Appraisal process. (Information on NICE's health technology evaluation processes is available at https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/changes-to-health-technology-evaluation).

References

1. Macmillan Cancer Support (2021) Causes and risk factors of prostate cancer. Accessed January 2026

2. National Disease Registration Service (2025) Cancer Registration Statistics. Accessed: Date Accessed January 2026

3. National Prostate Cancer Audit (2025) State of the Nation Report 2025. Accessed January 2026

4. Bouchelouche K, Choyke PL, Capala J. Prostate specific membrane antigen- a target for imaging and therapy with radionuclides. Discov Med. 2010 Jan;9(44):55-61.