UROLOGICAL SOCIETY OF AUSTRALIA AND NEW ZEALAND

Position Statement

Theranostics in Advanced Prostate Cancer Management

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Subject:	Patient Care	**Distribution:**		External	
Authorised by:	Board of Directors	**Approved Date:**	28.02.2025	Review Date:	Feb 2028

Purpose and Scope

This Position Statement has been developed by the Urological Society of Australia and New Zealand for our urologist members to provide guidance on the role of theranostics for managing advanced prostate cancer.

Position statement

1. Theranostics in Advanced Prostate Cancer

The increasing use of PSMA PET as a diagnostic tool has expanded the role of theranostics in managing advanced prostate cancer. This approach often utilises optimised PSMA-targeting molecules such as 68Gallium-labeled PSMA for diagnosis, while therapeutic radiopharmaceuticals labelled with β-emitting isotopes (lutetium-177 or yttrium-90) or α-emitting isotopes (actinium-225) can be used to treat metastatic castrate-resistant prostate cancer (mCRPC).

177Lu-PSMA-617 is the most extensively studied PSMA therapeutic radiopharmaceutical. ^{177}Lu-PSMA I&T is another available alternative.

2. The Evidence

2.1 TheraP Trial

In the randomized phase II TheraP trial, men with mCRPC suitable for cabazitaxel were randomly assigned to receive either upto 6 cycles of [177Lu]Lu-PSMA-617 or cabazitaxel. The primary endpoint was a PSA response (≥50% reduction from baseline). After a median follow-up of 35.7 months, this was achieved in 66% of the [177Lu]Lu-PSMA-617 group versus 37% of the cabazitaxel group ($p<0.0001$). At 36 months, overall survival was similar between the two groups.

2.2 VISION Trial

The phase 3 VISION trial evaluated 177Lu-PSMA-617 in men with mCRPC previously treated with at least one androgen-receptor-pathway inhibitor and one or two taxane regimens. Patients were randomised to receive either 177Lu-PSMA-617 or standard care. At a median follow-up of 20.9 months, 177Lu-PSMA-617 plus standard care significantly improved both imaging-based progression-free survival and overall survival compared to standard care alone. An updated study supported the safety of up to 6 cycles of 177Lu-PSMA-617 in patients who are clinically benefiting and tolerating the therapy.

2.3 Side effect profile

- Between 1%(TheraP) -7% (Vision) patients discontinued LU-PSMA due to toxicity.

  In the TheraP trial Grade 3-4 adverse events were less frequent with [177Lu]Lu-PSMA-617 compared to cabazitaxel (33% vs. 53%). with high rates of thrombocytopenia with Lu-PSMA-617.

- In the Vision trial, the incidence of grade 3 or higher adverse events was higher with 177Lu-PSMA-617 compared to standard of care; quality of life was not negatively impacted.

3. Criteria for Consideration of Theranostics

All patients who are being considered for theranostics should be discussed at a Multidisciplinary setting and imaging reviewed.

The following criteria should be considered for 177Lu-PSMA-617 therapy:

- Metastatic castration-resistant prostate cancer.
- Prior treatment with at least one androgen-receptor–pathway inhibitor and at least one taxane regimen.
- At least one PSMA-positive metastatic lesion (uptake greater than liver parenchyma) (defined as SUVmax > 15 at a single site of disease and SUVmax >10 at all sites of measurable disease) and no PSMA-negative lesions.
- ECOG performance status score of 0-2.
- Use of ligand therapy outside of these criteria should only be within approved clinical trials.

4. Access

Currently, theranostics is not available on the medicare benefits schedule and access is via clinical trials or self-funding

5. References

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- Chi KN, Armstrong AJ, Krause BJ, Herrmann K, Rahbar K, de Bono JS, Adra N, Garje R, Michalski JM, Kempel MM, Fizazi K. *Safety Analyses of the Phase 3 VISION Trial of [177Lu] Lu-PSMA-617 in Patients with Metastatic Castration-resistant Prostate Cancer*. European Urology. 2024 Apr 1;85(4):382-91.

Related Documents

- None

Roles and responsibilities

- The USANZ Board of Directors is the approval authority for Position Statements and other Policies that relate to patient care.
- The Genitourinary Oncology Specialty Advisory Group (GUSAG) is responsible for the development and review of position statements and policies that relate to genitourinary oncology medical matters and for making recommendations to the Board of Directors.

Revision history

Version	Date	Notes	By
Draft	2024	Drafted	GUSAG
1.0	28 Feb 2025	Approved	Board of Directors

Review date

This position statement will be reviewed by the Speciality Advisory Group and the Board of Directors. The next review will be in February 2028.

Contact

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