

MSAC Application 1823

**Lutetium-177 vipivotide tetraxetan
(¹⁷⁷Lu-PSMA-617) for prostate specific
membrane antigen (PSMA)-positive, taxane-
naïve patients with metastatic castrate
resistant prostate cancer (mCRPC)**

Applicant: Novartis Pharmaceuticals Australia Pty Limited

PICO Confirmation

Summary of PICO criteria to define question(s) to be addressed in an Assessment Report to the Medical Services Advisory Committee (MSAC)

Table 1 PICO Set for ¹⁷⁷Lu-PSMA-617 in taxane-naïve patients with mCRPC

Component	Description
Population	Adult patients who have: - progressive mCRPC, <i>AND</i> - have received: - at least one ASI (e.g. abiraterone/enzalutamide/darolutamide), <i>AND</i> - no prior taxane chemotherapy or ¹⁷⁷Lu-PSMA-617 for prostate cancer, <i>AND</i> - been assessed as PSMA-positive (SUV_{max} >15 at a single site of disease <i>AND</i> SUV_{max} >10 at all sites of measurable disease), <i>AND</i> - have been determined by a multidisciplinary team to be suitable for ¹⁷⁷Lu-PSMA-617 treatment. Progressive mCRPC defined as: - rise in PSA of >2 ng/mL confirmed by two tests a minimum of two weeks apart, <i>AND/OR</i> - evidence of new soft tissue or bone metastases on diagnostic imaging CT as per established guidelines (such as RECIST criteria as published by the European Organisation for Research and Treatment of Cancer or the Response Evaluation Criteria in PSMA-Imaging Criteria).
Prior tests	Whole body PSMA PET study (PSMA-positive: SUV _{max} >15 at ≥1 disease site <i>AND</i> SUV _{max} >10 at all sites of measurable disease required to proceed to therapy).
Intervention	¹⁷⁷Lu-PSMA-617 (Pluvicto) therapy and prior diagnostic test (bundle). <u>¹⁷⁷Lu-PSMA-617 therapy:</u> ¹⁷⁷Lu-PSMA-617 administered intravenously every 6 weeks, up to a maximum of 6 doses, with or without medical castration with a GnRH.
Comparators	- Docetaxel - Best supportive care
Outcomes	<u>Safety (of therapy*):</u> - Any/overall AE (primary outcome for safety evaluation) - any grade AE - serious AE (Grade ≥3) - death due to AE - treatment-emergent AE - treatment-emergent AE leading to adjustment of dose - treatment-emergent AE leading to discontinuation - Radiation exposure (patients, carers, staff) <u>Effectiveness (of therapy*):</u> - Radiographic PFS (primary outcome for effectiveness evaluation) - OS - PFS - Time to symptomatic skeletal event - Time to radiographic soft tissue progression - Time to chemotherapy - PSA response - Quality of life - Pain

Component	Description
	<u>Healthcare system:</u> - Cost of diagnostic testing and therapy - Total Australian Government healthcare costs of proposed treatment (including cost of treatment received and cost offsets due to treatment avoided)
Assessment questions	- What is the safety, effectiveness and cost-effectiveness of ¹⁷⁷Lu-PSMA-617 therapy compared to docetaxel OR best supportive care in patients with mCRPC who have confirmed disease progression based on pathology and/or imaging following treatment with an ASI and are unsuitable for taxane-based chemotherapy - What costs for the Australian healthcare system are associated with the proposed treatment (therapy and diagnostic test)? - What is the total Australian Government healthcare expenditure (including cost of tests and treatment received and cost offsets due to treatment avoided) associated with the proposal?

Abbreviations: AE, adverse event; ASI, androgen-receptor signalling inhibitor; BPI-SF, Brief Pain Inventory – Short Form; CT, computed tomography; GnRH, gonadotropin-releasing hormone; Lu, lutetium; mCRPC, metastatic castration-resistant prostate cancer; OS, overall survival; PET, positron emission tomography; PFS, progression-free survival; PSA, prostate specific antigen; PSMA, prostate specific membrane antigen; RECIST, Response Evaluation Criteria in Solid Tumours; RLT, radioligand therapy; SUV_{max}, maximum standardised uptake value.

Notes:

PSMA-positivity and disease progression are defined to align with descriptors of MBS items currently supporting claims for lutetium PSMA-targeted therapy in the mCRPC setting in Australia.

Prior exposure to taxane-based chemotherapy for an indication other than prostate cancer does not preclude a patient from being considered taxane-naïve under this definition.

* Safety and effectiveness of the proposed PSMA PET study as a diagnostic test for determining suitability for Lutetium-177 PSMA therapy to treat mCRPC has been accepted by MSAC.

Purpose of application

An application requesting Medicare funding to enable subsidisation of Lutetium-177 vipivotide tetraxetan (¹⁷⁷Lu-PSMA-617) product-based prostate-specific membrane antigen (PSMA)-targeted treatment of metastatic castration-resistant prostate cancer (mCRPC) in patients who have received at least one androgen receptor signalling inhibitor (ASI) (i.e. as a second-line treatment) was received from Novartis Pharmaceuticals Australia Pty Ltd by the Department of Health, Disability and Ageing. The application requests the following:

- 1) amendment to existing MBS PSMA PET item 61528 for the determination of eligibility for Lutetium-177 therapy; specifically, broadening the population defined as eligible to proceed to therapy if PSMA-positive, to include taxane-naïve patients
- 2) reimbursement of ¹⁷⁷Lu-PSMA-617 via a radiopharmaceutical fund
- 3) using implementation options to separately subsidise the administrative costs related to the proposed therapy.

Effective 1 July 2025, 3 MBS items were established in Australia to subsidise PSMA-targeted Lutetium-177 treatment of mCRPC in patients who have received at least one ASI and at least one taxane-based chemotherapy (i.e. as a third-line treatment) (Appendix 1). These MBS items were created in the wake of MSAC's advice to the Minister for Health and Ageing after consideration of an evidence evaluation performed for a funding application (Application 1686 and 1686.1)¹ received from a group of academic specialists, which was co-sponsored by the Australasian Association of Nuclear Medicine Specialists. This earlier request was to fund the proposed treatment using a different product—¹⁷⁷Lu PSMA imaging scan and therapy (¹⁷⁷Lu PSMA i&t)—in patients with mCRPC and confirmed disease progression after one androgen signalling inhibitor (ASI) and one taxane-based chemotherapy (MSAC 2024).

PICO criteria

Population

The proposed population is adult patients with mCRPC; with confirmed disease progression based on pathology and/or imaging following treatment with an ASI and deemed unsuitable for, or appropriate to delay taxane-based chemotherapy for prostate cancer; and a PSMA-positive whole-body PSMA positron emission tomography (PET) scan.

PSMA-positivity is defined in alignment with MBS item 16050: Maximum Standardised Uptake Value (SUV_{max}) >15 at a single site of disease and SUV_{max} >10 at all sites of measurable disease.

Disease progression is defined in alignment with MBS item 16055 definitions for the continuation of ¹⁷⁷Lu-PSMA therapy:

- rise in prostate serum antigen (PSA) >2 ng/mL confirmed by two tests a minimum of 2 weeks apart, and/or

¹ MSAC Public Summary Document (PSD), Application No. 1686.1 – 177-Lutetium PSMA i&t for metastatic castrate resistant prostate cancer, April 2024 MSAC meeting.

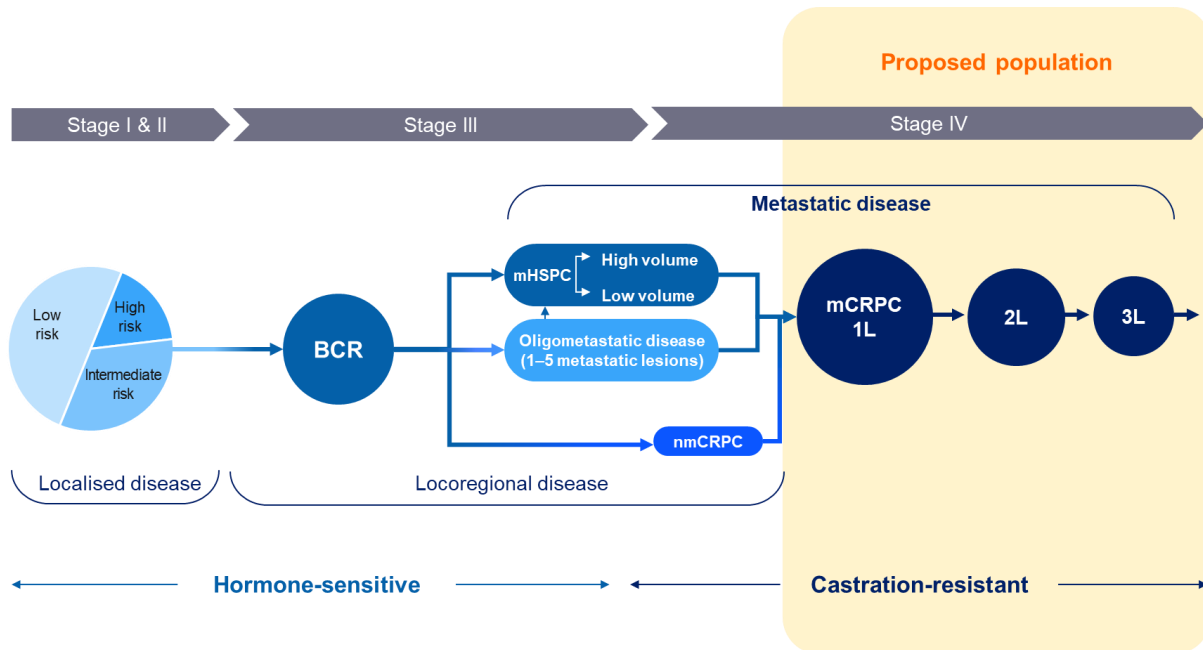
- evidence of new soft tissue or bone metastases on diagnostic CT as per established guidelines (e.g. RECIST criteria [Response Evaluation Criteria in Solid Tumours] as published by the European Organisation for Research and Treatment of Cancer or the RECIP criteria [Response Evaluation Criteria in PSMA-Imaging]).

Figure 1 illustrates the natural history of prostate cancer, which is the third most commonly diagnosed cancer worldwide and responsible for over 350,000 deaths annually (Bray et al. 2018). Recent estimates suggest that around 3,000 patients in Australia die annually from mCRPC (MSAC 2024). Approximately 1 in 6 Australian males will be diagnosed with prostate cancer in their lifetime (Cancer Australia 2026). There is an increasing incidence of this cancer in younger patients (Williams et al. 2025). Most patients (82%) will be diagnosed in the early stages of disease (Stage I or II) where the prognosis is generally good, although cancers developing in younger patients are reported to have a more aggressive phenotype (AIHW 2025). Despite treatment, 10–20% of patients with prostate cancer will progress to mCRPC, with most having metastases at the time of diagnosis (Kirby, Hirst & Crawford 2011). Approximately 60% of non-metastatic castration-resistant disease will develop to mCRPC (Malone et al. 2022). The proportion of patients diagnosed with de novo metastatic disease is around 4% (AIHW 2025).

In Australia and internationally, mCRPC has a poor prognosis, with median survival of 3–4 years (Chowdhury et al. 2020; Francini et al. 2019; Westgeest et al. 2021; Williams et al. 2025). mCRPC has severe morbidity impacts, with adverse effects associated with the cancer and with treatments for the cancer. Australian patients also report feeling ignored within the health system, fear/uncertainty about their futures, concerns about treatment effects, predominately physical effects and financial concerns, concerns about accessible care related to geographic location, ill health and financial cost of treatment and acceptance of their situation (Chambers et al. 2018). Patients with mCRPC reportedly experience lower quality of life (QoL), greater severity of symptoms, more psychological distress, increased suicide risk and greater unmet care needs than those with localised disease (Chambers et al. 2018; Holmstrom et al. 2019). Skeletal-related adverse events (SREs) are commonly associated with the treatment of mCRPC and the bone-tropic pattern of the cancer as it progresses. SREs are known to be associated with clinically meaningful adverse effects on QoL (MSAC 2024).

Patients with prostate cancer are managed by a lead physician (e.g. urologist, medical oncologist) and, where possible, a comprehensive multidisciplinary team (MDT). mCRPC patients will have undergone extensive pathology and imaging testing to confirm diagnosis and the stage and extent of disease. Such tests may include physical examination, digital rectal examination, measurement of PSA levels, multiparametric MRI, biopsy, bone scans and PET/computed tomography (CT) scans. Evidence of biochemical or radiographic recurrence, despite castrate levels of testosterone in the setting of existing metastatic disease, confirms a diagnosis of mCRPC.

Figure 1 Overview of prostate cancer



Abbreviations: 1L, first line; 2L, second line; 3L, third line; BCR, biochemical recurrence; mHSPC, metastatic hormone-sensitive prostate cancer; mCRPC, metastatic castration-resistant prostate cancer; nmCRPC, non-metastatic castration-resistant prostate cancer.

Source: Novartis Data on File, 2026.

To be considered for treatment with ^{177}Lu -PSMA-617, a patient must have confirmed disease progression (based on pathology and/or imaging) following treatment with an ASI and be confirmed PSMA-positive based on PSMA PET scan. mCRPC patients considered appropriate candidates for treatment will be referred by their lead specialist for a PSMA PET scan to determine eligibility and suitability for ^{177}Lu -PSMA-617 treatment. For eligible patients, ^{177}Lu -PSMA-617 will be administered within an accredited nuclear medicine facility or hospital, typically as an outpatient service.

According to international prostate cancer clinical practice guidelines, the optimum treatment pathway for mCRPC varies depending on patient risk factors and disease characteristics. In mCRPC, treatment options consist of an ASI (also referred to as androgen receptor pathway inhibitor [ARPI]), docetaxel, ^{177}Lu -PSMA-617, cabazitaxel or palliative care. Treatment decisions depend on prior therapies received and patient preference, informed by the advice of a relevant treating physician (Fizazi et al. 2026; Kratochwil et al. 2023; Spratt et al. 2025).

Furthermore, in the absence of clinical or objective criteria that can be used to define when a patient is unsuitable for docetaxel or when treatment with docetaxel should be delayed, a case-by-case determination by MDT review is considered best practice.

Presently, ^{177}Lu -PSMA-617 is the only Lutetium-177 product listed by the Therapeutic Goods Administration (TGA) for use in Australia to treat mCRPC. It is listed with the product name Pluvicto. The TGA indication is currently for treatment of adult patients with PSMA-positive mCRPC who have been treated with androgen receptor pathway inhibition and taxane-based chemotherapy. A draft of the updated indication submitted for change to the TGA registration is detailed in Table 2.

Table 2 TGA-submitted updated indication for Pluvicto (change in bold)

Product name:	PLUVICTO
Active ingredients:	lutetium (¹⁷⁷ Lu) vipivotide tetraxetan
Sponsor:	Novartis Pharmaceuticals Australia Pty Ltd
TGA summary indication Pluvicto is indicated for the treatment of adult patients with prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor (AR) pathway inhibition and taxane-based chemotherapy. Pluvicto (lutetium [¹⁷⁷Lu] vipivotide tetraxetan) is proposed as a treatment for adults with advanced prostate cancer that has spread and no longer responds to hormone therapy. It is used in patients when the cancer shows a specific marker (called PSMA) and after patients have already been treated with hormone-blocking medicines and, in some cases, chemotherapy.	

Sources: Therapeutic Goods Administration report, October 2025 (for existing approval); Application material for the proposal.

In Australia, for patients with mCRPC whose disease has progressed following treatment with an ASI and who have not yet received chemotherapy, routine treatment options are limited to docetaxel or palliative care. However, some patients choose to forego treatment with docetaxel due to its toxicity profile and associated impact on QoL, while others are deemed to be unfit for chemotherapy by their treating physician (Al-Batran et al. 2015; Singer & Srinivasan 2012). The Drug Utilisation Sub-Committee² analysis indicates that most patients (71%) receive palliative care following an ASI and around 14% receive docetaxel (PBAC 2021). Thus, there is unmet need for second-line treatment options for patients with progressive mCRPC following an ASI. Based on the estimates provided in the application, of approximately 4,024 patients in Australia with mCRPC, 1,207 of them (30%) would receive the proposed intervention in Year 1, with utilisation increasing by 10% annually to 2,817 patients (70%) by Year 5.

The application's description of the proposed population for funding concludes with a summary of the rationale for proposing a broadening of the eligibility criteria of the MBS diagnostic item for Lutetium-177 therapy to include the proposed taxane-naïve population:

1. Aside from best supportive care, Lutetium-177 therapy is the only treatment option for patients who prefer to avoid taxane-based chemotherapy due to its impact on QoL. While switching to an alternative ASI may be considered in some countries, in Australia this is not routine practice because only treatment with one ASI is subsidised per lifetime.

International guidelines, including those of the National Comprehensive Cancer Network (NCCN) and the European Society for Medical Oncology (ESMO), now recommend use of ¹⁷⁷Lu-PSMA-617 for select patients who are taxane-naïve (the proposed patient population) (Fizazi et al. 2026; Spratt et al. 2025). The application states that this recommendation is expected to be reflected in the forthcoming TGA indication for ¹⁷⁷Lu-PSMA-617 in the mCRPC setting. The shift in guideline recommendations towards the use of ¹⁷⁷Lu-PSMA-617 before or instead of taxane chemotherapy for selected patients is supported by the outcomes of the Phase III PSMAfore trial (Fizazi, Chi, et al. 2025; Fizazi, Morris, et al. 2025; Morris et al. 2024). For this application, 'taxane-naïve' refers to patients with mCRPC who have not previously received taxane-based chemotherapy in the hormone-sensitive or castration-resistant prostate cancer setting. Prior exposure to taxane-based chemotherapy for an indication other than prostate cancer does not preclude a patient from being considered 'taxane-naïve' under this definition.

² Olaparib PSD, para 5.2, March 2021 PBAC Meeting.

PASC confirmed the applicant-proposed population for the evidence evaluation, as outlined in the PICO Set above. PASC recommended clarification that 'taxane-naïve' refers to patients who have not received taxane-based chemotherapy in the prostate cancer setting. PASC noted advice from the applicant's clinical expert that patients who have received taxane-based chemotherapy for a different cancer than prostate cancer would be considered 'taxane-naïve' in the mCRPC setting.

PASC noted that lutetium-177 therapies, including the proposed agent (¹⁷⁷Lu-PSMA-617) and ¹⁷⁷Lu PSMA i&t, are currently subsidised in Australia via the MBS as third-line treatments. Thus, the proposed population has significant implications for clinical treatment pathways and existing funding arrangements.

PASC noted that international clinical guidelines do not support the routine substitution of ¹⁷⁷Lu-PSMA-617 for docetaxel as a second-line treatment for patients with mCRPC. Specifically, US guidelines recommend ¹⁷⁷Lu-PSMA-617 for patients who are considered appropriate to delay a taxane-based chemotherapy, while European guidelines recommend ¹⁷⁷Lu-PSMA-617 for patients who are not immediate candidates for docetaxel. PASC noted the applicant's clinical experts' advice provided during the meeting, that is, that there are no clearly defined clinical criteria that can reliably identify these patients in practice. In the absence of such criteria—and recognising that treatment decisions are informed by a range of factors including disease characteristics, PSMA imaging results, socioeconomic considerations and patient preferences—PASC considered that eligibility for the proposed treatment could be restricted to patients who have a positive PSMA imaging result and have been assessed by a multidisciplinary team as a suitable candidate for ¹⁷⁷Lu-PSMA-617 treatment.

PASC heard from the applicant's clinical expert that rechallenge with ¹⁷⁷Lu-PSMA-617 may be considered for some taxane-naïve patients, although this is expected to occur infrequently. In light of this advice, PASC suggested that a once-per-lifetime treatment restriction be considered for the relevant MBS item eligibility criteria.

Intervention

The intervention proposed in the application is PSMA-targeted radionuclide therapy using ¹⁷⁷Lu-PSMA-617, after diagnostic imaging to determine suitability to receive this therapy.

¹⁷⁷Lu-PSMA-617 is a novel radioligand therapy (RLT) comprising a PSMA-targeting vector that binds with high affinity and specificity to PSMA, which is often highly expressed in mCRPC. The treatment is a targeted intravenous radiotherapy that enters the cancer cell via the PSMA receptor. PSMA is overexpressed in prostate cancer and is further upregulated in metastatic and castrate-resistant disease. High PSMA expression correlates with disease progression and is an independent prognostic biomarker of poorer clinical outcomes (Hupe et al. 2018; Nagaya et al. 2020; Paschalis et al. 2019). The radioactive atom ¹⁷⁷Lu delivers cytotoxic radiation specifically to prostate cancer lesions expressing PSMA, maximising the therapeutic effect while minimising off-target effects.

A 1 mL solution of ¹⁷⁷Lu-PSMA-617 contains 1,000 MBq of lutetium (¹⁷⁷Lu) vipivotide tetraxetan at the date and time of calibration. The total amount of radioactivity per single-dose vial is 7,400 MBq ± 10% at the date and time of administration. Given the fixed volumetric activity of 1,000 MBq/mL at the date and time of calibration, the volume of solution in the vial can range from 7.5 mL to 12.5 mL to provide the required amount of radioactivity at the date and time of administration. Each millilitre of solution contains up to 0.312 mmol (7.1 mg) of sodium (TGA 2025).

Treatment with ^{177}Lu -PSMA-617 has been shown to prolong survival, reduce risk of radiographic progression, reduce time to first symptomatic skeletal event, and improve QoL (Hofman et al. 2021; Patell et al. 2023; Sartor et al. 2021). The efficacy and safety of ^{177}Lu -PSMA-617 therapy has been demonstrated in patients with mCRPC having confirmed disease following ASI and taxane chemotherapy, as well as in patients with mCRPC and disease progression following ASI but no taxane chemotherapy (Poon et al. 2025; Satapathy, Swayamjeet, Sahoo & Bal 2023). The VISION phase III RCT is a pivotal study in the clinical evidence base relating to the proposed intervention, even though it assessed the treatment in PSMA-positive mCRPC patients who had been treated with an ASI and taxane-based chemotherapy. The results showed that ^{177}Lu -PSMA-617 plus standard of care (allowed treatments included but not limited to abiraterone and enzalutamide) significantly prolonged median radiographic progression-free survival (PFS) (hazard ratio [HR] 0.40; 95% confidence interval [CI] 0.29 to 0.57) and overall survival (OS) (HR 0.62; 95% CI 0.52 to 0.74) compared with standard of care alone (Sartor et al. 2021).

The literature suggests that a range of factors including extent of disease, detailed history of prior treatments, different treatment protocols and concomitant standard anticancer treatments, along with ^{177}Lu -PSMA RLT influences patient PSA response and critical patient outcomes such as OS (Yadav et al. 2019).

The application relates that manufacturing of ^{177}Lu -PSMA-617 for use in Australia is carried out internationally only once a patient is scheduled and confirmed for treatment. The product is then shipped to the nominated facility within a specific timeframe to ensure the patient receives the correct dose. A stable supply chain exists for ^{177}Lu -PSMA-617 in Australia.

Therapy

The application proposes a ^{177}Lu -PSMA-617 dosage regimen of 7,400 MBq intravenously every 6 weeks (± 1 week) up to a total of 6 doses, or until disease progression or unacceptable toxicity, as per the recommendation in the Australian Product Information. Medical castration with a gonadotropin-releasing hormone (GnRH) analogue is recommended for continuation in patients not surgically castrated. Following treatment, the patient will be routinely monitored for response to treatment, side effects and disease progression to determine suitability for subsequent doses. Upon cessation of ^{177}Lu -PSMA-617, the lead physician will determine with the patient the next appropriate course of treatment.

The ^{177}Lu -PSMA-617 dose may be administered intravenously as an injection via syringe, or as an infusion using the gravity method or peristaltic pump method.

Management of severe or intolerable adverse reactions may require temporary dose interruption, dose reduction or permanent discontinuation of ^{177}Lu -PSMA-617 treatment. If treatment delay due to an adverse reaction persists for more than 4 weeks, treatment discontinuation may be considered. The dose may be reduced by 20% only once (to a dose of 5,900 MBq); the dose should not be re-escalated. If a patient has further adverse reactions that would require an additional dose reduction, treatment with ^{177}Lu -PSMA-617 must be discontinued.

Regarding other medical services that must be delivered concomitantly with the proposed therapy, the application relates that an oral dose of 8 mg dexamethasone is administered at the time of injection to minimise the chance of nausea or transient increase in pain. Approximately one week prior to treatment, patients will be required to have blood tests (haematological, kidney function, liver function) to confirm

medical and physical fitness to receive treatment. After the infusion, patients will remain isolated until radiation levels reduce to the safe government level for discharge.

It is proposed that the Lutetium PSMA therapy be administered by recognised nuclear medicine specialists (i.e. full membership of Australasian Association of Nuclear Medicine Specialists) in designated facilities. In Australia, nuclear medicine is an advanced speciality that requires specific training. ¹⁷⁷Lu-PSMA-617 is an RLT and should only be used by or under the control of healthcare professionals who are specifically qualified and experienced in the safe use and handling of radiopharmaceuticals, and whose experience and training has been approved by the appropriate governmental agency authorised to license the use of radiopharmaceuticals. Administration and delivery of ¹⁷⁷Lu-PSMA-617 cannot be delegated to another health professional. The application notes that relevant guidelines for the safe delivery of RLT in practice have been developed by the Society of Nuclear Medicine and Molecular Imaging and the European Association of Nuclear Medicine (Kratochwil et al. 2023).

Prior diagnostic test

The test proposed in the application is the whole-body PSMA PET scan currently funded via MBS item 61528 for patients treated with at least one taxane chemotherapy. To proceed to ¹⁷⁷Lu-PSMA-617 therapy, the PSMA PET study result for patients with no prior taxane chemotherapy is the same as that for taxane-treated patients. This is described in MBS item 16050, that is, PSMA-positive is defined as SUV_{max} >15 at a single site of disease and SUV_{max} >10 at all sites of measurable disease after disease progression (Appendix 1).

PASC confirmed that the intervention defined in the PICO Set was appropriate.

Comparator(s)

The comparators nominated in the application are docetaxel and palliative care (best supportive care), on the basis that these are the current standards of care for most taxane-naïve mCRPC patients that progress following ASI.

Docetaxel (taxane-based chemotherapy) is PBS funded³ and TGA approved for use in mCRPC and several other cancers, including breast cancer, non-small cell lung cancer, ovarian cancer and head and neck cancer (TGA 2023). Specific indications for docetaxel use in prostate cancer state: 'Indicated for the treatment of patients with androgen independent (hormone refractory) prostate cancer' (TGA 2023).

Docetaxel is administered as a one-hour infusion every 3 weeks in the outpatient setting. Oral prednisone or prednisolone is administered twice daily, commencing day 1 and continuing through each cycle. In addition, patients should be pre-treated with oral dexamethasone at 12 hours, 3 hours and 1 hour before infusion. Docetaxel is a cytotoxic drug with specific requirements for safe handling and waste management. Relevant outpatient healthcare resources are required to deliver treatment (trained staff, infusion chair etc). No prerequisite diagnostic tests are required for administration of docetaxel.

³ <https://pbs.gov.au/medicine/search?term=10148D-10158P>

Palliative care for mCRPC patients involves a holistic MDT focused on maintaining the patient's QoL while meeting their health and supportive care needs. This includes access to specially trained palliative care staff, medical and allied professionals, hospital-related services and medicines such as opioids.

According to the application, it is likely that most patients will prefer ¹⁷⁷Lu-PSMA-617 over docetaxel or no further treatment (i.e. best supportive care) after an ASI, due to favourable QoL and a different but manageable safety profile. As a result, docetaxel will likely be an alternative treatment option for patients who may progress following treatment with ¹⁷⁷Lu-PSMA-617.

The application states that ASI is not a relevant comparator, as it is subsidised in Australia for use only once per lifetime. The application further argued that ¹⁷⁷Lu PSMA i&t is not an appropriate comparator because it is currently subsidised for patients who have received at least one ASI and one taxane-based chemotherapy, and therefore these patients are at a later stage of disease and more clinically progressed than the proposed population in this application, and therefore not directly comparable.

In the application, the PSMAfore trial is presented as the primary evidence supporting the claim of superior effectiveness and non-inferior safety. This RCT did not evaluate either of the proposed comparators (Fizazi, Chi, et al. 2025; Fizazi, Morris, et al. 2025; Morris et al. 2024). Instead, the comparator in the PSMAfore trial was a change in ASI (Refer to Table 3 for an outline of the trial).

The application acknowledges the lack of alignment between the comparator used in the clinical evidence and the comparators proposed for evaluation. It provides 2 justifications for using the PSMAfore ASI arm as a proxy for current standard of care. Firstly, there are no direct head-to-head studies comparing ¹⁷⁷Lu-PSMA-617 to docetaxel or palliative care. Secondly, there is substantial unmet clinical need, with most patients (71%) receiving no subsequent treatment after progression on an ASI (olaparib PSD, para 5.2, March 2021 PBAC meeting). In this context, patients are frequently offered continuing ASI, implying that change in ASI is a reasonable proxy for standard of care.

The assessment group's literature scoping identified 2 trials comparing the proposed intervention with docetaxel. However, both studies are small and the results from one trial are currently only available from conference proceedings (Chi KN, SF, Ding K, Bauman G, Emmenegger U, Hotte SJ, et al. 2025; Chi KN, SF, Ding K, et al. 2026) (Table 3).

Systematic reviews identified during the assessment group's literature scoping suggest that potentially relevant noncomparative evidence from single-arm studies may also be available for consideration (Belabaci et al. 2025; Patell et al. 2023; Sadaghiani et al. 2022; Satapathy, Swayamjeet, Sahoo & Bal 2023).

Table 3 Trial evidence in support of the effectiveness and safety claim

Study design (trial name; ID) (citations)	N	Population	Intervention	Comparator	Outcomes	Notes
Submitted in the application PICO set						
RCT, Phase III (PSMAfore; NCT04689828) (Fizazi, Chi, et al. 2025; Fizazi, Morris, et al. 2025; Morris et al. 2024)	468	Taxane-naïve, PSMA-positive mCRPC patients with progressive disease following ARPI	¹⁷⁷ Lu-PSMA-617 (7.4 GBq IV every 6 weeks x 6 cycles)	ARPI change (abiraterone or enzalutamide)	Primary: rPFS Secondary: OS (key secondary endpoint), rPFS2, QoL, PSA-RR, Pain (BPI-SF), TTSE, TTSTP; TTCT, AEs	Patients could crossover from the comparator arm to ¹⁷⁷ Lu-PSMA-617 upon confirmation of rPFS; no bi-directional crossover design in trial, thus conclusions cannot be made about the optimal sequencing of change in ARPI vs second-line ¹⁷⁷ Lu-PSMA-617 treatment. While the trial provides relevant direct evidence in the review-eligible and funding-proposed population, it is important to note limitations that may reduce relevance: 1) a very small proportion of included patients had a taxane-based chemotherapy treatment >12 months before randomisation (exact proportion and number is unclear, although appears from studying the table comparing characteristics of patients across the 2 groups to be around 2%; 2) change in ARPI was the comparator; 3) proportion of patients included with liver metastases was low (<6% in treatment arm, 3% in comparator arm).
Identified during literature scoping to inform the PICO Set						
RCT, Phase II (PLUDO; NCT04663997) Results published as conference abstracts only (Chi KN, SF, Ding K, Bauman G, Emmenegger U, Hotte SJ, et al. 2025; Chi KN, SF, Ding K, et al. 2026)	199	Chemotherapy-naïve mCRPC patients progressing after ARPI; PSMA PET positive disease Excluded if >50% of extra-osseous lesions or >5 cm soft tissue lesions PSMA negative; adequate end-organ function; prior docetaxel for mHSPC permitted if ≥12 months prior	¹⁷⁷ Lu-PSMA-617 (7.4 GBq IV every 6 weeks x 6 cycles)	Docetaxel (75 mg/m ² every 3 weeks x 12 cycles)	Primary: rPFS Secondary: OS, rPFS2, PSA decline, AEs, QoL	Patients could crossover from the comparator arm to ¹⁷⁷ Lu-PSMA-617 upon confirmation of rPFS. Not all patients had no prior taxane chemotherapy, some had docetaxel ≥12 months before.

Study design (trial name; ID) (citations)	N	Population	Intervention	Comparator	Outcomes	Notes
RCT, Phase II (CTRI/2019/12/022 282) (Satapathy, S. et al. 2022)	45	Patients with mCRPC on Ga-PSMA-11 PET/CT with significant PSMA expression. Significant PSMA expression defined as tracer avidity of $\geq 80\%$ of lesions being significantly (≥ 1.5 times) greater than that of normal liver, with no lesions having uptake less than that of liver. Only chemotherapy-naïve patients considered for inclusion; patients with prior treatment of NAADs included. Patients with histological evidence of sarcomatous, spindle-cell or small-cell differentiation, and those with Sjogren syndrome excluded.	^{177}Lu -PSMA-617 (6.0–7.4 GBq IV every 8 weeks x 4 cycles)	Docetaxel (75 mg/m ² every 3 weeks, x 10 cycles)	Primary: PSA-RR Secondary: best objective response rate, molecular response rate, PFS, AEs, QoL	

Abbreviations: AE, adverse event; BPI-SF, Brief Pain Inventory – Short Form; ARPI (i.e. ASI), androgen receptor pathway inhibitor therapy; CAD, coronary heart disease; CT, computed tomography; mCRPC, metastatic castration-resistant prostate cancer; mHSPC, metastatic hormone-sensitive prostate cancer; NAADs, non-atherosclerotic arterial diseases; OS, overall survival; PET, positron emission tomography; PFS, progression-free survival; PSA, prostate-specific antigen; PSA-RR, prostate-specific antigen response rate, defined according to Prostate Cancer Clinical Trials Working Group-3 as proportion of patients achieving $\geq 50\%$ decline in PSA from baseline; PSMA, prostate-specific membrane antigen; RCT, randomised controlled trial; rPFS, radiographic-confirmed progression-free survival; TTCT, time to chemotherapy, defined as time from randomisation to initiation of the first subsequent chemotherapy or death, whichever occurs first; TTSE, time to first symptomatic skeletal event; TTSTP, time to soft tissue progression; QoL, quality of life

Notes: Robust searches to identify potentially relevant studies should not be considered to have been performed by the assessment group to inform this list of studies.

PASC questioned why docetaxel would be proposed as a comparator for a proposed population that may include patients determined as unsuitable for taxane-based chemotherapy.

PASC accepted the comparators nominated by the applicant and noted that the key evidence informing this application is the PSMAfore RCT, which evaluated ¹⁷⁷Lu-PSMA-617 against the comparator of a change in ASI. PASC heard from the applicant that the PSMAfore trial represents the principal source of evidence for the effectiveness and safety of the intervention in the proposed population of interest. However, PASC noted that the comparator used in the only direct head-to-head study (PSMAfore RCT), that being a change in ASI, does not align with docetaxel, which was one of the Australian-relevant comparators identified for the assessment. Therefore, PASC considered that indirect evidence comparing a change in ASI against docetaxel is required to evaluate the applicability of the study, and the outcomes adjusted accordingly if necessary.

Outcomes

Patient health outcomes

The patient health outcomes proposed for the clinical evidence evaluation are as follows.

Safety

- Any/overall adverse event (AE) (primary outcome for the safety evaluation)
 - Any grade AE
 - Serious AE (Grade ≥3)
 - Death due to AE
 - Treatment-emergent AE
 - Treatment-emergent AE leading to adjustment of dose
 - Treatment-emergent AE leading to discontinuation
- Radiation exposure (patients, carers, staff)

Effectiveness

- Radiographic PFS (primary outcome for effectiveness evaluation)
- OS, defined as time from randomisation to death due to any cause
- PFS
- Time to symptomatic skeletal event
- PSA response (including PSA50 response, defined as proportion of patients who achieved ≥50% decrease in PSA from baseline, confirmed by second PSA measurement at ≥4 weeks via laboratory test confirmation)
- QoL, as measured via validated instrument (e.g. EQ-5D-5L, European Quality of Life [EuroQol] 5-dimension 5-level questionnaire or FACT-P, Functional Assessment of Cancer Therapy – Prostate questionnaire)
- Pain, as measured via validated instrument (e.g. BPI-SF, Brief Pain Inventory – Short Form questionnaire)

All quantified effect measures are eligible for inclusion, with hazard ratio expected to be the measure used for most continuous outcomes. All follow-up timepoints are eligible for inclusion. It is proposed that any differences in follow-up time across studies will inform the data analysis and interpretation.

Healthcare resource use

- Costs associated with the intervention (therapy and diagnostic test)
- Total Australian Government healthcare expenditure (including cost of treatment received and cost offsets due to treatment avoided)

PASC considered the proposed clinical outcomes for the evidence evaluation to be appropriate. However, PASC noted that the financial evaluation should report outcomes separately by relevant payer perspectives and incorporate the costs associated with all components of the intervention.

PASC noted if the new arrangement funds ¹⁷⁷Lu-PSMA-617 at a higher effective price, post-taxane patients may not receive equivalent financial subsidies or experience different financial arrangements for payment of the service. Therefore, PASC considered the assessment should model the cost of applying any new ¹⁷⁷Lu-PSMA-617 funding arrangement to the existing post-taxane population. This will allow Government to understand the full equity and budget implications across both populations.

Clinical management algorithms

The application presented current (Figure 2) and proposed (Figure 3) clinical management algorithms, informed by a review of the literature including available clinical guidelines. The literature review findings were presented as a separate document along with the draft PICO and other application material.

The routine treatment pathway currently followed in Australia for patients with mCRPC is as follows. First-line options include the addition of an ASI (e.g. abiraterone, enzalutamide, apalutamide, darolutamide) to androgen deprivation therapy. For patients with disease progression who received an ASI, taxane-based chemotherapy is routinely offered, with best supportive care the alternative. Switching to a different ASI is uncommon, partly because this is determined to be not as effective as taxane-based chemotherapy, but also because the PBS in Australia restricts eligibility for funding of abiraterone and enzalutamide to once per lifetime (regardless of whether this is subsidised under a metastatic or non-metastatic indication). After ASI and docetaxel/cabazitaxel, ¹⁷⁷Lu-PSMA-617, and best supportive care are the options.

The application's description of the current clinical management pathway aligns well with that described as routine in the TGA listing for Pluvicto (October 2025). Although, this also highlights that the main reason for second-line use of cytotoxic chemotherapy agents is that these are the only agents that have significantly prolonged OS in clinical trials in males with mCRPC and no prior chemotherapy (TGA 2025).

In the application, the proposed change in the clinical management pathway for treatment of mCRPC is for ¹⁷⁷Lu-PSMA-617 to be stepped up to become a second-line treatment. This would ensure that the proposal is congruent with leading prostate cancer clinical guideline recommendations for ¹⁷⁷Lu-PSMA-617 therapy in the mCRPC setting (Fizazi et al. 2026; Spratt et al. 2025). The NCCN prostate cancer guideline⁴ states: 'Lu-177-PSMA-617 is a treatment option for patients with ≥1 PSMA-positive lesion and/or metastatic

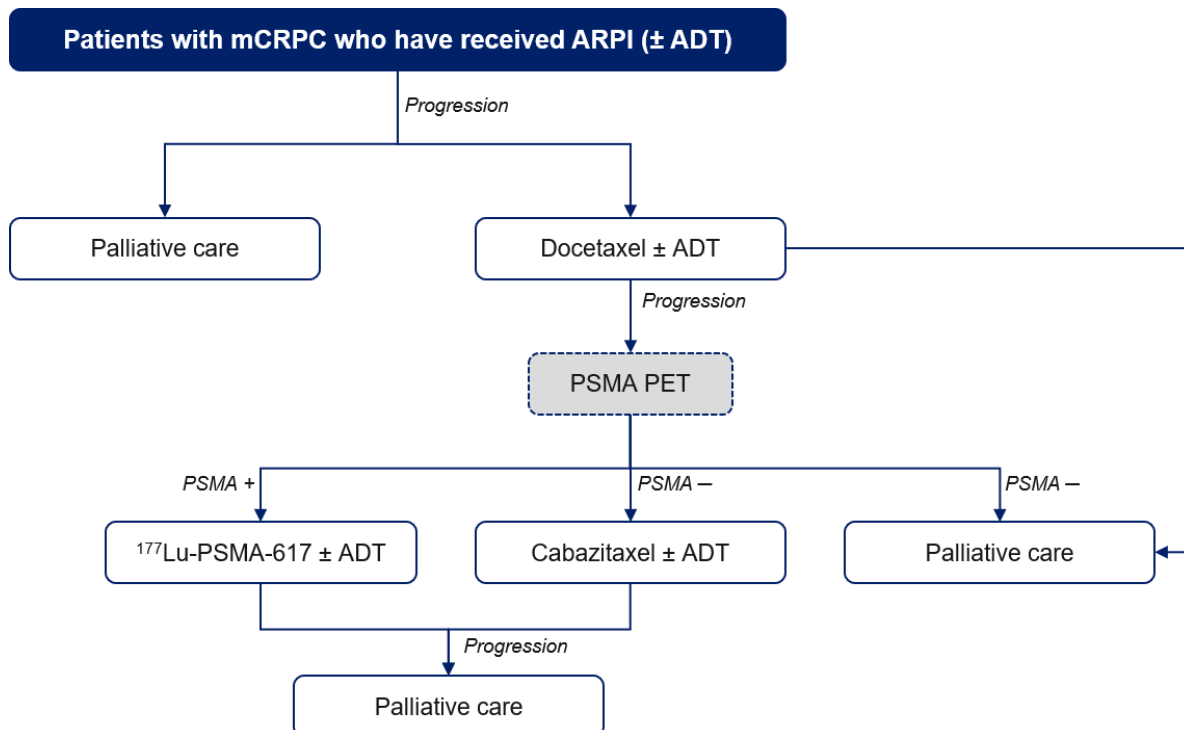
⁴ Spratt et al., 2025, 'Prostate Cancer, Version 3.2026, NCCN Clinical Practice Guidelines In Oncology', *Journal of the National Comprehensive Cancer Network*, vol. 23, no. 11, pp. 469-93.

disease that is predominately PSMA-positive and with no dominant PSMA-negative metastatic lesions who have been treated previously with androgen receptor-director therapy and a taxane-based chemotherapy who are considered appropriate to delay a taxane-based chemotherapy’. This recommendation is supported by evidence from the PSMAfore trial, the main trial presented in the application to support the clinical claim (Morris et al. 2024), and the VISION RCT (Sartor et al. 2021) that evaluated ¹⁷⁷Lu-PSMA-617 plus standard care versus standard care alone in patients with mCRPC who had progressed after at least one ASI and one or more taxane-based chemotherapy regimens. Similarly, the ESMO clinical guideline for the diagnosis, treatment and follow-up of advanced and metastatic prostate cancer conditionally supports the use of ¹⁷⁷Lu-PSMA-617 in selected taxane-naïve patients (Appendix 2). Specifically, it states: ‘¹⁷⁷Lu-PSMA-617 is approved in patients with PSMA-positive lesions who are not immediate candidates for docetaxel.’

PASC acknowledged the position of international prostate cancer guidelines that ¹⁷⁷Lu-PSMA-617 should not be considered as a routine substitute for docetaxel as a second-line treatment for patients with mCRPC.

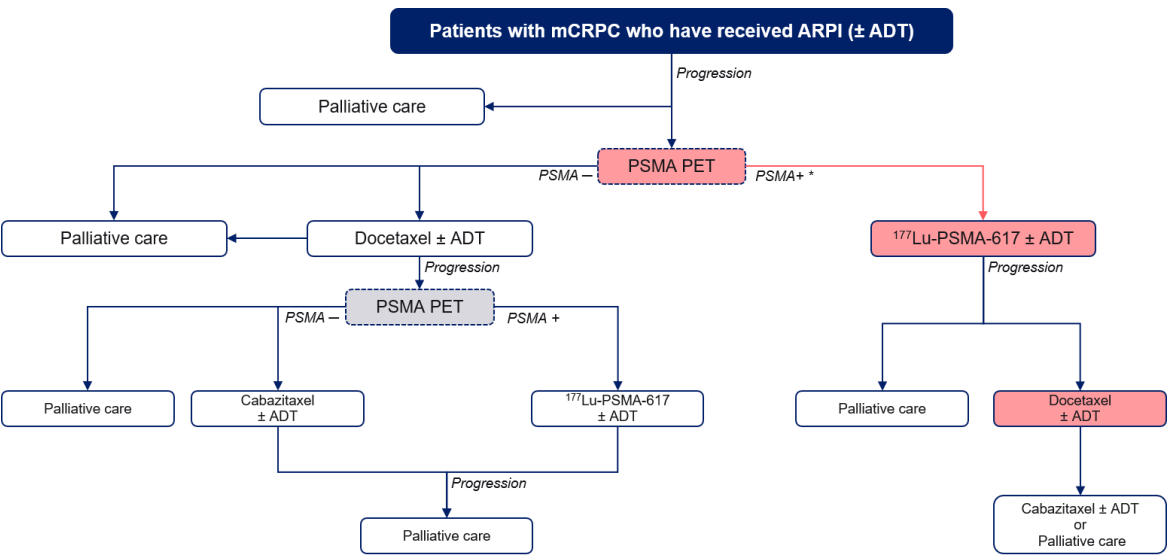
PASC noted advice from the applicant's clinical expert that while PSMA positivity is a prerequisite for treatment with ¹⁷⁷Lu-PSMA-617, treatment suitability is determined on a case-by-case basis, taking into account factors such as the extent of PSMA expression, disease aggressiveness, age, frailty, psychosocial and socioeconomic considerations, and patient preference. As these factors are typically evaluated by MDT review, PASC suggested that the proposed clinical management algorithm clarifies that ¹⁷⁷Lu-PSMA-617 (+ADT) is recommended only for select PSMA-positive patients who have received at least one prior ARPI and have been assessed by an MDT as suitable for treatment.

Figure 2 Current management algorithm for the proposed intervention and relevant comparators



Abbreviations: ADT, androgen deprivation therapy; ARPI, androgen receptor pathway inhibitor; mCRPC, metastatic castration-resistant prostate cancer; PSMA, prostate-specific membrane antigen; PET, positron emission tomography
Source: Application PICO, pg. 12.

Figure 3 Proposed clinical management algorithm for the proposed intervention and relevant comparators



Abbreviations: ADT, androgen deprivation therapy; ARPI, androgen receptor pathway inhibitor; mCRPC, metastatic castration-resistant prostate cancer; PSMA, prostate-specific membrane antigen; PET, positron emission tomography

Note: * In cases where patients are determined by a multidisciplinary team to be suitable for ¹⁷⁷Lu-PSMA-617 treatment.

Proposed economic evaluation

The application claimed that ¹⁷⁷Lu-PSMA-617 treatment is superior to current standard of care (i.e. taxane-based chemotherapy or best supportive care) in clinical effectiveness and non-inferior in safety.

The application did not consider whether there may be differences in treatment effects between patients who receive ¹⁷⁷Lu-PSMA-617 treatment in those deemed unsuitable for a taxane-based chemotherapy or those suitable to delay taxane-based chemotherapy, and separate claims were not presented for these populations. Consideration of potential treatment effect differences between these subgroups may be informative during the subsequent evidence assessment, although the ability to explore any effect modification is likely to be limited by the available evidence.

Based on the clinical claim, the proposed type of economic evaluation is a cost-effectiveness analysis and cost-utility analysis (Table 4).

PASC accepted the nominated economic analysis.

Table 4 Classification of comparative effectiveness and safety of proposed intervention compared with its main comparator and guide to most suitable economic evaluation

Comparative safety	Comparative effectiveness			
	Inferior	Uncertain	Noninferior ^b	Superior
Inferior	Health forgone: need other supportive factors	Health forgone possible: need other supportive factors	Health forgone: need other supportive factors	? Likely CUA
Uncertain ^a	Health forgone possible: need other supportive factors	?	?	? Likely CEA/CUA
Noninferior ^b	Health forgone: need other supportive factors	?	CMA	CEA/CUA
Superior	? Likely CUA	? Likely CEA/CUA	CEA/CUA	CEA/CUA

Abbreviations: CEA, cost-effectiveness analysis; CMA, cost-minimisation analysis; CUA, cost-utility analysis.

Notes: ^a 'Uncertainty' covers concepts such as inadequate minimisation of important sources of bias, lack of statistical significance in an underpowered trial, detecting clinically unimportant therapeutic differences, inconsistent results across trials, and trade-offs within the comparative effectiveness and/or comparative safety considerations

^b Adequate assessment of 'noninferiority' is the preferred basis for demonstrating equivalence.

Proposal for public funding

The application suggests the proposed intervention could be funded via 2 different mechanisms, one being items listed on the MBS (Table 5 and Table 7), and the other a separate radiopharmaceutical fund for the supply of the therapeutic component of the service (Table 6). For treatments where the MBS is not a suitable funding mechanism, the Government may consider alternative implementation and funding approaches. Any consideration of a funding model which varies from the MBS would require detailed policy development and consultation by the department, and Government agreement. No such program is currently in place, however, funding for the components for the proposed intervention can all be funded under the broader Medicare scheme.

MBS item 61528 amendment for diagnostic imaging services

The application proposes that the diagnostic imaging service described in MBS item 61528 be amended per Table 5. Suggested amendments to the item descriptors appear in italicised text for additions proposed by the applicant and blue text for additions proposed by the assessment group. These amendments will expand the patient population under the existing item to include the proposed patient population to determine eligibility for ¹⁷⁷Lu-PSMA-617 treatment in the proposed patient population.

Table 5 Proposed amendment to MBS item 61528

Category 5 – Diagnostic Imaging Services
MBS item 61528 Whole body PSMA PET study, performed for the assessment of suitability for Lutetium-177 PSMA therapy in a patient with metastatic castrate resistant prostate cancer, <i>a) after progressive disease has developed while undergoing prior treatment with at least one androgen receptor signalling inhibitor but no prior exposure to taxane chemotherapy in the prostate cancer setting, and determined by a multidisciplinary team to be suitable for ¹⁷⁷Lu-PSMA-617 treatment, or</i> <i>b) after progressive disease has developed while undergoing prior treatment with at least one taxane chemotherapy and at least one androgen receptor signalling inhibitor</i>
Fee: \$1,300 Benefit: 75% = \$975.00 85% = \$1,195.50*

Notes: Italicised text indicates proposed amendment to item by the applicant.

Blue text indicates proposed amendment to item by the assessment group following the PASC meeting.

* 85% benefit reflects the 1 November 2025 Greatest Permissible Gap (GPG) of \$104.50. All out-of-hospital Medicare services that have an MBS fee of \$697 or more will attract a benefit that is greater than 85% of the MBS fee – being the schedule fee less the GPG amount. The GPG amount is indexed annually on 1 November in line with the Consumer Price Index (CPI).

The application requested fee for the amended MBS item is consistent with those currently listed for MBS item 61528. MBS data shows that the average patient out-of-pocket cost for Item 61528 is \$300.00 and almost all services are provided out-of-hospital (85% benefit). The proposed item descriptor change is unlikely to affect that.

Radiopharmaceutical fund for reimbursement of ¹⁷⁷Lu-PSMA-617

The application requests reimbursement via a radiopharmaceutical fund to enable mCRPC patients to access and receive treatment with ¹⁷⁷Lu-PSMA-617, independent of the MBS. The Department of Health, Disability and Ageing is considering RLT funding and implementation options through the broader Medicare scheme. A Government decision on how RLTs will be funded has not been made. The clinical and economic evaluation of this application will consider the proposed service conceptually as a Medicare service and reflect the full cost of delivery (including the radiopharmaceutical). MSAC's role is unchanged for this application, and the clinical and economic assessment will consider the full cost of the service (including the radiopharmaceutical).

Recommended patient eligibility criteria for treatment are presented in Table 6. The applicant claims that these are guided by the PSMAfore clinical trial (Morris et al. 2024). Patients must have PSMA-positive mCRPC, progressive disease following treatment with ASI, and have not been exposed to taxane-based chemotherapy in the hormone-sensitive or castration-resistant prostate cancer setting. Importantly, prior exposure to taxane-based chemotherapy for an indication other than prostate cancer does not preclude a patient from being considered taxane-naïve under this definition. It is recommended PSMA-positive is defined in alignment with current MBS item 16050, that is, SUVmax >15 at a single site of disease and SUVmax >10 at all sites of measurable disease.

Disease progression is defined as:

- rise in PSA >2 ng/mL confirmed by two tests a minimum of 2 weeks apart, and/or
- evidence of new soft tissue or bone metastases on diagnostic CT as per established guidelines (e.g. RECIST criteria or RECIP criteria).

This aligns with the current MBS definition of disease progression for continuation of ¹⁷⁷Lu-PSMA therapy (MBS Item 16055). MBS Item 16055 also includes a follow-up single-photon emission CT scan (SPECT) within 36 hours. The rationale for the inclusion of the SPECT in MBS item 16055 was to confirm radioligand uptake and biodistribution following treatment and to provide information that may assist clinicians in assessing treatment response and informing decisions regarding subsequent treatment cycles. This was not a requirement in the pivotal clinical trials for ¹⁷⁷Lu-PSMA-617 (PSMAfore and VISION) (Morris et al. 2024), and it is not included in the proposed restriction criteria on the grounds that the requirement for post-treatment imaging should be based on clinical practice, need and feasibility.

As mentioned, the choice between available therapies, including docetaxel and ¹⁷⁷Lu-PSMA-617, is individualised and informed by prior treatments, disease characteristics, clinician judgement and patient preference. As such, decisions regarding the use of docetaxel, the deferral of docetaxel, or the selection of an alternative therapy such as ¹⁷⁷Lu-PSMA-617 are best made on a case-by-case basis via MDT review.

Table 6 Proposed criteria for treatment with ¹⁷⁷Lu-PSMA-617 for mCRPC patients

Category	Therapeutic medicine
Restriction	Authority required
Clinical criteria	• Patient must have confirmed metastatic castration-resistant prostate cancer. • Patient must be confirmed prostate-specific membrane antigen (PSMA)-positive based on PSMA PET scan (defined as SUV_{max} >15 at a single site of disease and SUV_{max} >10 at all sites of measurable disease). • Patient must have progressive disease following a) treatment with at least one ARPI, and b) have not been exposed to taxane-based chemotherapy in the hormone-sensitive or castration-resistant prostate cancer setting, and c) determined by a multidisciplinary team to be suitable for ¹⁷⁷Lu-PSMA-617 treatment. • Patient must not have received treatment with ¹⁷⁷Lu-PSMA-617 for prostate cancer. Treatment is applicable once per cycle and must not be subsidised beyond whichever comes first: i) up to a maximum of 6 cycles (once per lifetime), ii) disease recurrence/progression.

Note: Blue text indicates proposed amendment to item by the assessment group following the PASC meeting.

MBS funding for associated services

The application notes there is very little difference between administration of antineoplastic therapies such as PBS-listed docetaxel and administration of ¹⁷⁷Lu-PSMA-617. Patients treated with ¹⁷⁷Lu-PSMA-617 will have a consultation with their specialist prior to receiving treatment; blood tests will be reviewed to confirm medical and physical fitness to receive treatment; intravenous infusion of treatment will occur and general monitoring after treatment before discharge home. These are all standard administrative services required for delivery of antineoplastic treatment.

Following treatment infusion, patients will remain isolated in the nuclear medicine facility until radiation levels reduce to the safe government limit for discharge (25uSv/hour at 1 metre). Radiation levels are monitored using small devices stocked in facilities where radiation levels are required to be monitored.

The application requests that associated administrative services necessary for administration of ¹⁷⁷Lu-PSMA-617 are subsidised separately utilising existing MBS items (Table 7). It is argued that this aligns

with the administration of other antineoplastic treatments delivered in the outpatient setting (e.g. chemotherapy).

Table 7 Required administrative services for treatment with ¹⁷⁷Lu-PSMA-617

Resource	MBS item(s)	Fee*
Specialist consultation	MBS item 110: Professional attendance at consulting rooms or hospital, by a consultant physician in the practice of the consultant physician's specialty (other than psychiatry) following referral of the patient to the consultant physician by a referring practitioner-initial attendance in a single course of treatment	\$183.35
	MBS item 116: Professional attendance at consulting rooms or hospital, by a consultant physician in the practice of the consultant physician's specialty.	\$91.70
Blood tests (haematology, kidney function, liver function)	MBS item 65070: Full blood examination	\$17.80
	MBS item 12524: Renal function test (without imaging procedure)	\$189.55
	MBS item 66512: Liver function test	\$17.70
IV infusion of treatment	MBS item 13950: Parenteral administration of one or more antineoplastic agents	\$129.30

Abbreviations: IV, intravenous.

Note: * The fees have been updated to reflect indexation of the schedule fees from 1 July 2026.

The department has advised that ¹⁷⁷Lu-PSMA-617 would not constitute a cytotoxic chemotherapy agent or monoclonal antibody therapy as legislated in MBS item 13950. As the safety and supervision requirements for administration of RLT differ to that of cytotoxic chemotherapy, a new MBS item for administration of ¹⁷⁷Lu-PSMA-617 is the most appropriate option. Consistent with the MBS principle that each item represents a complete medical service, a proposed item and fee should include all components ordinarily required for safe and effective delivery of that service. Activities integral to the service would be expected to be covered by the primary item fee rather than funded separately, as is the case with Lutetium treatment MBS items 16050, 16055, and 16060. The application suggests bundled fee elements used in MSAC's consideration of Application 1744, lutetium for eligible patients with neuroendocrine tumours, which are shown in Table 8.

Table 8 Bundled fee elements for the proposed MBS administration item for ¹⁷⁷Lu-PSMA-617

Service element	Suggested fee (MBS item fees based off 1 July 2026 prices)
Theranostic specialist pre-treatment consultation fee	\$183.35 (based off MBS Item 110)
Theranostic specialist treatment supervision and follow up fee	\$129.30 (based off MBS Item 13950)
Post-administration SPECT/CT scan	\$400.00 (provided in MSAC 1744)
Radiation safety officer/physicist	\$75.00 (provided in MSAC 1744)
Total	\$787.65

Abbreviations: CT, computed tomography; SPECT, single-photon emission CT.

Notes: Blue text indicates amendments by the assessment group following the PASC meeting.

The fees have been updated to reflect indexation of the schedule fees from 1 July 2026.

Using the services identified in the application as required elements, a draft item with a schedule fee of \$788 for administering ¹⁷⁷Lu-PSMA-617 is proposed. The applicant is agreeable to the addition of a SPECT/CT scan after each treatment cycle. This is consistent with MBS Items 16050 and 16055 for the post-taxane chemotherapy population, using post-treatment SPECT/CT imaging to monitor treatment response and disease progression.

A draft MBS item for the administration of ¹⁷⁷Lu-PSMA-617 is shown in Table 9.

Table 9 Proposed MBS item for the administration of ¹⁷⁷Lu-PSMA-617 for mCRPC patients

Category	Therapeutic Procedures
Group	T3 - Therapeutic Nuclear Medicine
Sub-group	Subgroup 2 – Theranostics
Item XXXX	Patient preparation and administration of ¹⁷⁷Lu-PSMA-617, followed within 36 hours by whole body Lu-PSMA SPECT, for treatment of a patient with metastatic castrate resistant prostate cancer who: (a) is determined as PSMA-positive by PSMA PET (defined as SUV_{max} >15 at a single site of disease and SUV_{max} >10 at all sites of measurable disease) after disease progression, and (b) has had progression of disease following treatment with at least one ARPI, with no prior exposure to taxane-based chemotherapy in the hormone-sensitive or castration-resistant prostate cancer setting, and (c) determined by a multidisciplinary team to be suitable for ¹⁷⁷Lu-PSMA-617 treatment. (Includes the necessary patient preparation, administration, immediate patient aftercare required for the treatment cycle, and relevant consultation with the supervising specialist). Applicable once per cycle, for a maximum of 6 cycles (once per lifetime).
	Fee: \$788 Benefit: 75% = \$591.00 85% = \$683.50*

Notes: Blue text indicates proposed amendment to item by the assessment group following the PASC meeting.

* 85% benefit reflects the 1 November 2025 Greatest Permissible Gap (GPG) of \$104.50. All out-of-hospital Medicare services that have an MBS fee of \$697 or more will attract a benefit that is greater than 85% of the MBS fee – being the schedule fee less the GPG amount. The GPG amount is indexed annually on 1 November in line with the Consumer Price Index (CPI).

Consideration should be given as to whether existing MBS Items 16050 and 16055 require amendment to reflect that Lutetium therapy is generally applicable only once in a patient's lifetime, particularly if a radiopharmaceutical fund is introduced to support reimbursement under the newly proposed criteria (Table 6).

Informed by concerns raised during the meeting regarding the potentially high out-of-pocket costs associated with the proposed treatment, the documented concerns of Australians with prostate cancer regarding cost of treatment and financial implications (Chambers et al) and the resulting risk of inequity in access, PASC considered it important that the assessment clearly evaluates downstream impacts of the proposed population, including effects on treatment pathways, patient outcomes and associated financial implications from relevant payer perspectives. The applicant advised that inequitable access was not expected to be a significant concern because government funding was being sought to cover all costs associated with treatment delivery. PASC emphasised the need to assess any potential impacts on patient access and equity. Of particular PASC concern, was if ¹⁷⁷Lu-PSMA-617 were funded under different financial arrangements or at a higher effective price than that currently available to post-taxane patients through the MBS items 16050 and 16055, this could result in non-equivalent subsidies or different financial arrangements for payment of the same therapeutic service. To evaluate this further, PASC considered the assessment should also model the cost of applying any new ¹⁷⁷Lu-PSMA-617 funding arrangement to the existing post-taxane population in addition to the taxane naive population proposed in this application.

PASC noted that the funding model for the proposed treatment is yet to be decided. Thus, the various funding mechanisms described in the PICO Set should be regarded as proposals.

The applicant's clinical expert advised that a SPECT-CT scan undertaken after each cycle of ¹⁷⁷Lu-PSMA-617 treatment should be included in the proposed bundled MBS items.

PASC suggested a once-per-lifetime restriction for the therapeutic item descriptor.

PASC noted the need to revise the diagnostic MBS item descriptor to provide a clearer definition of 'taxane-naïve' to adequately capture those patients who have not previously received taxane-based chemotherapy for prostate cancer. PASC noted advice from the applicant's clinical expert that patients who have received taxane-based chemotherapy for a different cancer (other than prostate cancer) would be considered 'taxane-naïve' in the mCRPC setting.

Summary of public consultation input

PASC noted and welcomed consultation input from 7 organisations and 1 individual who was a consumer. The 7 organisations that submitted input were:

- ANZUP Cancer Trials Group Ltd
- APAC Telix Pharmaceuticals Australia
- Australasian Association of Nuclear Medicine Specialists (AANMS)
- Australian Diagnostic Imaging Association (ADIA)
- Oncothera Advocacy
- The Australian and New Zealand Society of Nuclear Medicine (ANZSNM)
- The Royal Australian and New Zealand college of Radiologists (RANZCR).

Consultation input was largely supportive of public funding for ¹⁷⁷Lu-PSMA therapy for PSMA-positive, taxane-naïve patients with mCRPC. RANZCR was unable to support the application in its current form due to concerns regarding access and the financial burden for patients. Consultation input raised concern regarding the proposed funding arrangements for ¹⁷⁷Lu-PSMA therapy and the potential for significant out-of-pocket costs for patients.

Consumer Experience

The individual consumer input described substantial benefit following ¹⁷⁷Lu-PSMA therapy, including a significant reduction in PSA levels and disease control. The consumer highlighted that affordable access to future treatment would support their ability to continue caring for their wife at home.

Oncothera Advocacy stated that people with mCRPC may experience bone pain, skeletal events, loss of independence and functional decline. It noted that preserving quality of life, functional independence and pain control are important treatment goals for patients, particularly where chemotherapy is unsuitable or not preferred.

Benefits and Disadvantages

The main benefits of public funding reported in the consultation input included delayed disease progression, maintenance of quality of life and an additional treatment option for patients for whom chemotherapy is unsuitable or not preferred. Consultation input also highlighted the potential to preserve functional independence, delay worsening of pain and improve patient outcomes.

The main disadvantage of public funding in the consultation input was equity of access to therapy and ensuring that out of pocket costs to patients were limited.

Population, Comparator (current management) and Delivery

The consultation input generally agreed with the proposed population. ANZSNM, ANSZUP and AANMS recommended aligning the population more closely with the PSMAfore trial by limiting the population to patients for whom taxane-based chemotherapy is being delayed, is unsuitable or is not preferred.

The consultation input agreed with the proposed comparator, stating that docetaxel and best supportive care were considered reflective of current Australian clinical practice following progression on an ARPI. Consultation input noted that current PBS restrictions do not allow ARPI switching for patients with disease progression but input agreed that using ARPI switching as a proxy was reasonable.

Other services identified as being needed before, with or after the intervention included PSMA PET/CT, specialist clinical assessment and multidisciplinary management. RANZCR recommended that metastatic directed therapy with stereotactic body radiation therapy (SBRT) should be considered prior to radioligand treatment.

MBS Item Descriptor and Fee

The consultation input disagreed with the proposed MBS item descriptors. All consultation received, including ANZSNM, ANZUP, AANMS, Telix and RANZCR recommended that the treatment descriptor be product agnostic rather than limited to a single proprietary ¹⁷⁷Lu-PSMA product. ANZSNM and AANMS recommended restricting administration of therapy to appropriately trained nuclear medicine specialists, while RANZCR considered that appropriately trained specialists from a range of clinical backgrounds should be eligible to provide the service. ANZSNM and AANMS also recommended mandatory inclusion of post-treatment SPECT imaging given its ability to provide important information for dosimetry, and potential clinically significant information such as disease progression or loss of PSMA positivity which may preclude further cycles of ¹⁷⁷Lu-PSMA treatment.

Consultation input agreed with the proposed MBS imaging fee but noted that no proposed fee was provided for the radioligand. ADIA stated that existing MBS items for ¹⁷⁷Lu-PSMA therapy include the cost of both imaging and therapy with a radioligand, and that the fee is based on the cost of a generic radioligand. All consultation input stated that there is currently a financial barrier to accessing ¹⁷⁷Lu-PSMA therapy due to the generic radioligand no longer being available for supply in Australia and the current need to access a significantly more expensive proprietary radioligand.

Additional Comments

Consultation input highlighted the importance of supply resilience and maintaining treatment availability across accredited public and private facilities. ANZSNM, ANZUP and AANMS supported hospital-based production of ¹⁷⁷Lu-PSMA products at appropriately accredited facilities.

PASC noted the feedback received during consultation was generally positive, however several caveats were identified. These included potential inequities in access arising from the limited availability of suitably trained and accredited specialists and the high out-of-pocket costs associated with treatment, which may disproportionately affect patients from lower-income households.

Next steps

PASC noted the applicant has elected to progress its application as an ADAR (Applicant Developed Assessment Report).

Applicant Comments on Ratified PICO

Novartis welcomes the PASC's confirmation of the PICO and acceptance of the key elements of the evidence framework. Novartis also acknowledges PASC's recognition that the therapeutic component, ¹⁷⁷Lu-PSMA-617 (Pluvicto®), and the administration services required for the safe delivery of treatment are distinct components of the proposed intervention, with consideration of a dedicated MBS administration item separate from reimbursement of the radiopharmaceutical treatment.

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Appendices

Appendix 1: Current MBS items subsidising Lutetium-177 suitability and therapy in mCRPC

Table 10 MBS item 61528 for whole body PSMA PET study to assess suitability for Lutetium 177 PSMA therapy in mCRPC

Category 5: Diagnostic imaging services	
MBS item 61528	Group 14 – Nuclear Medicine Imaging Subgroup 2 - PET
Whole body PSMA PET study, performed for the assessment of suitability for Lutetium 177 PSMA therapy in a patient with metastatic castrate resistant prostate cancer, after progressive disease has developed while undergoing prior treatment with at least one taxane chemotherapy and at least one androgen receptor signalling inhibitor.	
Fee: \$1,300.00 Benefit: 75% = \$975.00 85% = \$1,195.50	

Note: The fees have been updated to reflect indexation of the schedule fees from 1 July 2026.

Table 11 MBS item 16050 for treatment initiation of Lutetium 177 PSMA therapy in mCRPC

Category 3: Therapeutic procedures	
MBS item 16050	Group T3 – Therapeutic Nuclear Medicine Subgroup 2 - Theranostics
Administration of Lutetium 177 PSMA, followed within 36 hours by whole body Lu-PSMA SPECT, for treatment of a patient with metastatic castrate resistant prostate cancer who is: (a) PSMA-positive as determined by PSMA PET (defined as SUVmax >15 at a single site of disease and SUVmax >10 at all sites of measurable disease) after disease progression and (b) prior treatment includes at least one taxane chemotherapy and at least one androgen receptor signalling inhibitor. Applicable once per cycle, up to a maximum of 2 cycles in the initial treatment phase.	
Fee: \$8,208.00 Benefit: 75% = \$6,156.00 85% = \$8,103.50	

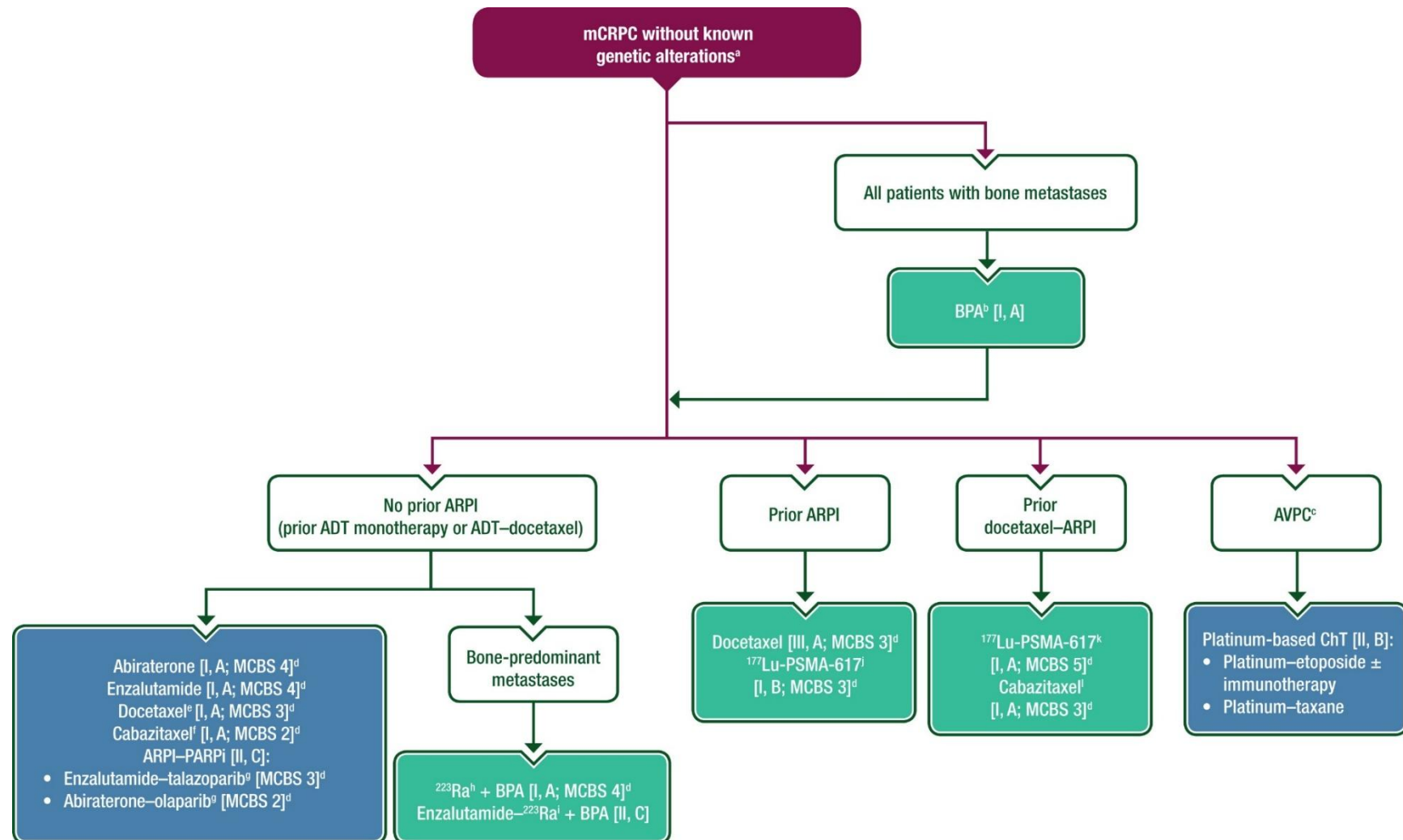
Note: The fees have been updated to reflect indexation of the schedule fees from 1 July 2026.

Table 12 MBS item 16055 for treatment continuation of Lutetium 177 PSMA therapy in mCRPC

Category 3: Therapeutic procedures	
MBS item 16055	Group 14 – Therapeutic Nuclear Medicine Subgroup 2 - Theranostics
Administration of Lutetium 177 PSMA, followed within 36 hours by whole body Lu-PSMA SPECT, for treatment of a patient with metastatic castrate resistant prostate cancer, if: (a) a service to which item 16050 applies has been provided; and (b) the patient has not developed disease progression while receiving Lutetium 177 PSMA for this condition. Applicable once per cycle, up to a maximum of 4 cycles in the continuing treatment phase.	
Fee: \$8,208.00 Benefit: 75% = \$6,156.00 85% = \$8,103.50	

Note: The fees have been updated to reflect indexation of the schedule fees from 1 July 2026.

Appendix 2: ESMO Clinical Practice Guideline (2026) for therapeutic management of mCRPC



Ratified PICO Confirmation – August 2026 PASC Meeting
Application 1823