MSAC Application 1823

^{177}Lutetium PSMA-617 for prostate specific membrane antigen (PSMA)-positive, taxane-naïve patients with metastatic castrate resistant prostate cancer (mCRPC)

Application for MBS eligible service or health technology

HPP Application number:
HPP200410

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

Submitting organisation:
NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LIMITED

Submitting organisation ABN:
18004244160

Application description

Succinct description of the medical condition/s:
The proposed population are adult patients with metastatic castration-resistant prostate cancer (mCRPC), who are confirmed prostate-specific membrane antigen (PSMA)-positive, have progressive disease following treatment with an androgen receptor inhibitor pathway inhibitor (ARPI) and are untreated with taxane-based chemotherapy in the hormone-sensitive or castration-resistant setting. Approximately 1 in 6 men will be diagnosed with prostate cancer in their lifetime. Prostate cancer is the most common cancer in Australian men. Most men are diagnosed and treated in earlier stages of disease. Despite treatment, some men will develop mCRPC. mCRPC is generally associated with the poorest prognosis, with real-world studies reporting median survival of between 3 and 4 years.

Succinct description of the service or health technology:
177Lu-PSMA-617 is a novel radioligand therapy (RLT) consisting of a PSMA-targeting vector that binds with high affinity and specificity to PSMA which is often highly expressed in mCRPC. 177Lu-PSMA-617 is the only Therapeutic Goods Administration approved RLT for mCRPC. The MSAC has previously assessed and recommended 177Lu-PSMA-617 for patients with PSMA-positive mCRPC who have previously been treated with ARPI and docetaxel. A PSMA PET scan is used to determine the level of PSMA expression and assess suitability for intravenous treatment with 177Lu-PSMA-617. The pivotal clinical trial in the proposed population demonstrates improved

treatment response, pain control and quality of life, as well as low toxicity compared to standard of care.

Application contact details

Are you applying on behalf of an organisation, or as an individual?

Organisation

Is the applicant organisation the organisation you are representing in the HPP today?

Yes

Applicant organisation name:

NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LIMITED

Application details

Please select the program through which the health technology would be funded:

Other

Specify the funding program:

Medicare Benefits Schedule and the broader Medicare program

Please provide justification for selecting the above program:

Reimbursement for radioligand therapy with 177Lu-PSMA-617 is proposed through the broader Medicare program.

The application also seeks to amend MBS item 61528 to expand the eligible patient population for determining access to 177Lu-PSMA-617 treatment.

What is the type of service or health technology?

Therapeutic

PICO sets

Application PICO sets:

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

Population

Describe the population in which the proposed health technology is intended to be used:

The proposed population are adult patients with metastatic castration-resistant prostate cancer (mCRPC), who are confirmed prostate specific membrane antigen (PSMA)-positive, have progressive disease following treatment with an androgen receptor inhibitor pathway inhibitor (ARPI) and are untreated with taxane-based chemotherapy in the hormone-sensitive or castration-resistant setting.
Prostate cancer is the most diagnosed cancer in Australia, accounting for approximately 30% of all male cancer diagnoses in 2025. Approximately 1 in 6 men will be diagnosed with prostate cancer in their lifetime (ACP, 2026). Most men (82%) will be diagnosed in the early stages of disease (i.e., Stage I and II) where prognosis is generally good (AIHW, 2025). Despite treatment, approximately 10% to 20% will progress to castration-resistant disease and studies suggest that most of these patients will have metastases at the time of developing castration resistant disease (i.e., mCRPC) (Kirby et al., 2011). Approximately 60% of non-metastatic castration-resistant disease will develop mCRPC (Malone et al., 2022). Only a small proportion (4.2%) of men will be diagnosed with de novo metastatic disease (AIHW, 2025). mCRPC is generally associated with the poorest prognosis, with real-world studies reporting median survival of less than 4 years and Australian data reporting median survival of 3 years (Francini 2019, Chowdhury 2020, Westgeest 2021; Williams et al., 2025). mCRPC significantly affects patient wellbeing due to persistent symptoms and impairment from both cancer and treatments. Australian men with mCRPC experience lower quality of life, 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).

Select the most applicable Medical condition terminology (SNOMED CT):

Hormone refractory prostate cancer

Intervention

Name of the proposed health technology:

Lutetium-177 vipivotide tetraxetan (177Lu-PSMA-617) (Pluvicto®)

Comparator

Nominate the appropriate comparator(s) for the proposed medical service (i.e. how is the proposed population currently managed in the absence of the proposed medical service being available in the Australian health care system). This includes identifying health care resources that are needed to be delivered at the same time as the comparator service:

Docetaxel or palliative care are the current standard of care for taxane-naïve mCRPC patients that progress following ARPI, making them the most appropriate comparators. 177Lu-PSMA is currently subsidised for patients that have had at least one ARPI and one taxane-based chemotherapy. Patients eligible for this treatment are later line and more progressed patients and are therefore not the same population as the proposed patient population in this application. As such, 177Lu-PSMA therapy is not an appropriate comparator.
In Australia, treatment with ARPIs is restricted to once per lifetime under the PBS criteria. Subsequently, treatment options for mCRPC patients who progress following an ARPI and are taxane-naive are limited to either docetaxel or palliative care. There are no head-to-head trials comparing the effectiveness of 177Lu-PSMA-617 to docetaxel or palliative care in the proposed patient population. Based on analysis by the Drug Utilisation Subcommittee (DUSC) of PBAC, most patients (71%) do not receive any subsequent treatment in the 18-24 months following novel hormone therapy. Therefore, in the absence of direct evidence comparing the proposed treatment to standard of care in the proposed population, the comparator arm of the study PSMAfore will be presented as a proxy for standard of care.

Outcomes

Outcome description – please include information about whether a change in patient management, or prognosis, occurs as a result of the test information:

The clinical claim will be assessed on radiographic progression-free survival as the primary outcome for effectiveness, and adverse events for safety. Additional secondary and exploratory outcomes for effectiveness include overall survival, progression-free survival, PSA50 response, time to symptomatic skeletal events, time to soft tissue progression, time to chemotherapy, and patient-related outcomes.
The diagnostic test PSMA PET has been assessed and considered clinically superior and cost-effective by MSAC. As such, effectiveness outcomes for the test (e.g., diagnostic accuracy) are not relevant.
mCRPC is an incurable disease associated with high morbidity and mortality. Natural progression often involves worsening symptoms such as fatigue and bone pain which can have negative impacts on quality of life. Improving survival and preserving quality of life are key treatment goals for patients living with mCRPC. Treatment decisions can be impacted by various factors. Up to 90% of patients develop bone metastases leading to severe bone pain from skeletal events like fractures and spinal cord compression. Studies have found that controlling or reducing bone pain is an important factor for mCRPC patients when considering their treatment options.
In Australia, current treatment options for the proposed mCRCP patient population are docetaxel or palliative care. Taxane-based chemotherapy may be deferred or avoided due to concerns from either the patient or physician about severe side effects that reduce quality of life, an assessment that the therapeutic benefits do not outweigh the risk, or because the patient's health makes taxanes unsuitable. This is supported by DUSC data that indicates only 14% of patients receive docetaxel in the 18-24 months following treatment with an ARPI.
Overall, PSMAfore demonstrates improved outcomes for taxane naïve mCRPC patients who have been treated with an ARPI compared to current standard of care. The results show that patients treated with 177Lu-PSMA-617 may experience improved survival through a significantly reduced risk of radiographic progression compared to standard of care. In addition, patients treated with 177Lu-PSMA-617 may experience better quality of life while on treatment due to delayed worsening and longer time to deterioration compared to current standard of care.
Prolonging time to progression and symptomatic skeletal event while maintaining quality of life are important considerations for mCRPC patients. 177Lu-PSMA-617 provides clinicians and patients with an alternative effective and safe treatment

option to docetaxel or palliative care in the first line mCPRC setting following treatment with an ARPI.

Specified restrictions for funding

Proposed item: AAAAA

Is the proposed item restricted?

Yes - restricted

Provide a short description of the restriction:

Proposed funding for 177Lu-PSMA-617 (Pluvicto®)

Please draft a proposed restriction to define the population and health technology usage characteristics that would define eligibility for funding:

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 SUVmax >15 at a single site of disease and SUVmax >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 setting.
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, ii) disease recurrence/progression.

Proposed price of supply:

TBC

Indicate the overall cost per patient of providing the proposed health technology:

TBC

How is the technology / service funded at present? (For example: research funding; State-based funding; self-funded by patients; no funding or payments):

177Lu-PSMA-617 is not currently funded for patients with mCRPC who are taxane naïve. 177Lu-PSMA-617 is currently subsidised on the MBS for patients with mCRPC

who have progressive disease following treatment with at least one ARRI and at least once taxane-based therapy.

Claims

In terms of health outcomes (comparative benefits and harms), is the proposed technology claimed to be superior, non-inferior or inferior to the comparator(s)?

Superior

Please state what the overall claim is, and provide a rationale:

The therapeutic conclusion is that 177Lu-PSMA-617 is superior to current standard of care in terms of clinical efficacy, and non-inferior in terms of safety. Currently, patients with mCRPC who have progressed following treatment with an ARPI and are taxane-naïve have limited treatment options, highlighting an unmet need for this population. The pivotal trial, PSMAfore, assessed the efficacy of 177Lu-PSMA-617 compared to ARPI. In Australia, PBS criteria restrict treatment with an ARPI to once per lifetime, leaving docetaxel or palliative care as the only available treatment options for patients (i.e., current standard of care). There are no head-to-head studies comparing 177Lu-PSMA-617 to docetaxel or palliative care. Data indicates that most patients (71%) do not receive any subsequent treatment following an ARPI. Given this, the clinical data from the PSMAfore ARPI arm is used as a proxy for current standard of care.
The clinical claim is based on rPFS, the primary outcome of PSMAfore, supported by secondary outcomes and adverse events. The clinical data demonstrates that 177Lu-PSMA-617 improves outcomes for taxane naïve mCRPC patients who have been treated with an ARPI compared to current standard of care:
- Statistically significant 59% reduced risk of radiographic progression or death.
- 59% risk reduction of symptomatic skeletal events or death.
- While on-treatment, patients treated with 177Lu-PSMA-617 appeared to be more stable with less pain compared to ARPI. Time to worsening of pain was delayed in the 177Lu-PSMA-617 arm.
- While on-treatment, patients treated with 177Lu-PSMA-617 experienced a higher quality of life and delayed time to deterioration.
The results show that patients treated with 177Lu-PSMA-617 may experience improved survival through significantly reduced risk of radiographic progression and a reduced risk of experiencing SSEs compared to standard of care, and better quality of life while on treatment.

Estimated utilisation

Estimate the prevalence and/or incidence of the proposed population:

There is limited data on the incidence and prevalence of mCRPC in Australia. Most patients will be diagnosed in the earlier stages of disease but data on the progression of disease is limited. Data indicates that 20% of patients will progress to castration-resistant disease and studies suggest that most of these patients will have metastases (i.e., mCRPC). Among those with non-metastatic castration-resistant disease, approximately 60% develop mCRPC. Given this, estimates are likely underestimated. Based on current available data, approximately 4,000 men have mCRPC.

Provide the percentage uptake of the proposed health technology by the proposed population:

Year 1 estimated uptake (%):

30%

Year 2 estimated uptake (%):

10%

Year 3 estimated uptake (%):

10%

Year 4 estimated uptake (%):

10%

Estimate the number of patients who will utilise the proposed technology for the first full year:

1,200

Will the technology be needed more than once per patient?

Yes, multiple times

Over what duration will the health technology or service be provided for a patient? (preferably a number of years):

Typically, within 1 year

Optionally, provide details:

Up to a maximum of 6 doses of 177Lu-PSMA-617 will be delivered to each patient. One dose is recommended every six weeks. The maximum doses of treatment are generally delivered within the course of one year.

What frequency will the health technology or service be required by the patient over the duration? (range, preferably on an annual basis):

Up to a maximum of 6 doses.

Consultation

List all entities that are relevant to the proposed service / health technology. The list can include professional bodies / organisations who provide, request, may be impacted by the service/health technology; sponsor(s) and / or manufacturer(s) who produce similar products; patient and consumer advocacy organisations or individuals relevant to the proposed service/health technology.

Entity who provides the health technology/service

Australian and New Zealand Society of Nuclear Medicine

The Australian and New Zealand Urogenital and Prostate Cancer Trials Group

GenesisCare

Australasian Association of Nuclear Medicine Specialists

Patient and consumer advocacy organisations relevant to the proposed service/health technology

Prostate Cancer Foundation Australia

ANZUP Cancer Trials Group consumer panel

Movember Foundation

Parliamentarians for prostate cancer

Relevant sponsor(s) and / or manufacturer(s) who produce similar products relevant to the proposed service or health technology:

Sponsors of current taxane-based chemotherapy

Regulatory information

Would the proposed health technology involve the use of a medical device, in-vitro diagnostic test, radioactive tracer or any other type of therapeutic good?

Yes

Has it been listed or registered or included in the Australian Register of Therapeutic Goods (ARTG) by the Therapeutic Goods Administration (TGA)?

Yes

Is the therapeutic good classified by the TGA as either a Class III or Active Implantable Medical Device (AIMD) against the TGA regulatory scheme for devices?

No

Please enter all relevant ARTG IDs:

ARTG ID	ARTG name
410282	PLUVICTO lutetium (177Lu) vipivotide tetraxetan 1000 MBq/mL solution for injection vial

Is the intended purpose in this application the same as the intended purpose of the ARTG listing(s)?

No

Provide details:

The TGA are currently considering 177Lu-PSMA-617 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 pathway inhibition (ARPI) therapy. 177Lu-PSMA-617 is already TGA approved 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 pathway inhibition (ARPI) and taxane-based chemotherapy.

Is the therapeutic good classified by the TGA as for Research Use Only (RUO)?

No