



# Therapeutic nuclear medicine therapy for metastatic castrate resistant prostate cancer

Last updated: 13 June 2025

- From **1 July 2025** two new items for <sup>177</sup>Lutetium (Lutetium) prostate specific membrane antigen (PSMA) therapy will be listed on the Medicare Benefits Schedule (MBS) for the treatment of patients with progressive or symptomatic metastatic castrate-resistant prostate cancer, where prior treatment has failed.
- A new whole-body PSMA positron emission tomography (PET) item will also be listed to determine a patient's suitability to undergo Lutetium PSMA therapy.
- Metastatic castrate-resistant prostate cancer is an advanced prostate cancer that has spread to other parts of the body and is not responding to hormone therapy.
- This change is relevant to health professionals who request, provide and claim Lutetium PSMA therapy under the MBS, as well as patients, private health insurers and hospitals.

## What are the changes?

Effective **1 July 2025**, the following changes will occur:

- One new item (61528) will be listed in the Diagnostic Imaging Services Table for a whole-body PSMA PET scan to assess a patient's eligibility for Lutetium PSMA therapy.
- Two new items (16050 and 16055) for initial and continuing Lutetium PSMA therapy will be listed in the General Medical Services Table to treat eligible patients with metastatic castrate-resistant prostate cancer where prior treatment has failed.

Private Health Insurance Classifications for the PSMA PET and Lutetium PSMA treatment items will be applied as follows:

### Diagnostic PSMA PET scan (item 61528)

- Clinical category: Support list (DI) (as for other diagnostic imaging services) of Schedule 5 of the [Private Health Insurance \(Complying Product\) Rules 2015](#).
- Procedure type: Type C of the [Private Health Insurance \(Benefit Requirements\) Rules 2011](#)

### Lutetium PSMA treatment (items 16050 and 16055)

- Clinical category: Chemotherapy, radiotherapy and immunotherapy for cancer, of the [Private Health Insurance \(Complying Product\) Rules 2015](#)
- Procedure type: Type C of the [Private Health Insurance \(Benefit Requirements\) Rules 2011](#)

## Why are the changes being made?

These new services will support people with metastatic castrate-resistant prostate cancer to access Lutetium PSMA treatment, improving survival rates and quality of life.

The Medical Services Advisory Committee (MSAC) recommended public funding for Lutetium PSMA therapy for advanced prostate cancer at their meeting in April 2024, and the Australian Government announced that the services will be listed from **1 July 2025** as part of the 2024-25 Mid-Year Economic and Fiscal Outlook.

Further details about MSAC Application 1686.1 can be found under [MSAC Applications](#) on the [MSAC website](#).

## What does this mean for requestors and providers?

Specialists and consultant physicians can request a whole-body PSMA PET scan (item 61528) for patients with metastatic castrate resistant prostate cancer, after progression of disease has developed despite treatment with chemotherapy and at least one androgen receptor signalling inhibitor. This diagnostic test will determine a patient's eligibility for Lutetium PSMA therapy.

Patients who are identified as eligible for Lutetium PSMA therapy can receive two cycles of therapy in the initial treatment phase (item 16050). If there has been no progression of disease during the initial treatment phase, these patients can receive continuing Lutetium PSMA therapy (item 16055), for up to a maximum of four cycles.

Items 16050 and 16055 are not limited to a particular Lutetium PSMA product. This is intended to facilitate patient access to treatment, noting the likely emergence of other Lutetium PSMA products in the future.

Note TN3.2 provides additional information on the use of Item 16055 for continuing therapy.

## How will these changes affect patients?

These new services will provide greater access to Lutetium PSMA treatment for eligible patients who have metastatic castrate-resistant prostate cancer, leading to improved health outcomes and quality of life.

Patients may be required to pay an upfront amount to their service provider to begin Lutetium PSMA treatment, and in some cases, this may be a significant amount.

Where the upfront payment is \$10,000 or more, a [Medicare claim form \(MS014\)](#) must be completed and submitted to Medicare by mail or in-person at a Services Australia service centre. These claims cannot be submitted online.

Medicare Safety Nets support people who have high out-of-pocket medical costs for MBS services which are provided out-of-hospital.

Under the Extended Medicare Safety Net (EMSN), once the out-of-pocket expenses for an individual or a family reach the relevant EMSN threshold amount, Medicare will cover up to 80% of any further out-of-pocket expenses for the remainder of the calendar year.

More information about Medicare claims and the EMSN, including the current calendar year EMSN thresholds, can be found on the [Services Australia](#) website.

Patients can view and manage their Medicare Safety Net and update their personal and bank account details to receive their Medicare benefit in their Medicare online account through [myGov](#), or by calling Medicare on 132 011.

## Who was consulted on the changes?

In addition to the MSAC consultation process, the Department of Health, Disability and Ageing (the department) consulted with a wide range of stakeholders representing experts across the diagnostic imaging, nuclear medicine and medical sector, as well as consumer representative groups and other stakeholders with expertise working with patients who have prostate cancer.

## How will the changes be monitored and reviewed?

The department regularly reviews the use of new and amended MBS items in consultation with the profession. Providers are responsible for ensuring Medicare services claimed using their provider number meet all legislative requirements. All Medicare claiming is subject to compliance checks and providers may be required to submit evidence about the services they bill. More information about the department's compliance program can be found on its website at [Medicare compliance](#).

## Where can I find more information?

The full item descriptor(s) and information on other changes to the MBS can be found on the [MBS Online website](#). You can also subscribe to future MBS updates by visiting '[Subscribe to the MBS](#)' on the MBS Online website.

The department provides an email advice service for providers seeking advice on interpretation of the MBS items and rules and the *Health Insurance Act 1973* and associated regulations. If you have a query relating exclusively to interpretation of the Schedule, you should email [askMBS@health.gov.au](mailto:askMBS@health.gov.au).

Private health insurance information on the product tier arrangements is available at [www.privatehealth.gov.au](http://www.privatehealth.gov.au). Detailed information on the MBS item listing within clinical categories is available on the [department's website](#). Private health insurance minimum accommodation benefits information, including MBS item accommodation classification, is available in the latest version of the *Private Health Insurance (Benefit Requirements) Rules 2011* found on the [Federal Register of Legislation](#). If you have a query in relation to private health insurance, you should email [PHI@health.gov.au](mailto:PHI@health.gov.au).

Subscribe to '[News for Health Professionals](#)' on the Services Australia website and you will receive regular news highlights.

If you are seeking advice in relation to Medicare billing, claiming, payments, or obtaining a provider number, please go to the Health Professionals page on the Services Australia website or contact Services Australia on the Provider Enquiry Line – 13 21 50.

The data file for software vendors when available can be accessed via the [Downloads](#) page.

## New item descriptors (to take effect 1 July 2025)

\* The Greatest Permissible Gap (GPG) has been applied to the out-of-hospital benefit (see asterisk below).

From 1 November 2024, the GPG is set at \$102.40. This means that all out-of-hospital Medicare services which have a schedule fee of \$683.00 or more will attract a Medicare benefit that is greater than 85% of the MBS fee.

<b>Category 5 – Diagnostic Imaging Services</b>
<b>Group I4 – Nuclear Medicine Imaging</b>
<b>Subgroup 2 – PET</b>
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, after progressive disease has developed while undergoing prior treatment with at least one taxane chemotherapy and at least one androgen receptor signalling inhibitor.  (R) (Anaes) Fee: \$1,300.00 Benefit: 85%: \$1,197.60*, 75%: \$975.00 <ul style="list-style-type: none"><li>• Private Health Insurance Classification:</li><li>• Clinical category: Support List (DI)</li><li>• Procedure type: Type C</li></ul>

### Category 3 - Therapeutic Procedures

#### Group T3 – Therapeutic Nuclear Medicine

##### Subgroup 2 – Theranostics

16050

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: \$8,000.00 Benefit: 85%: \$7,897.60\*, 75%: \$6,000.00

- Private Health Insurance Classification:
- Clinical category: Chemotherapy, radiotherapy and immunotherapy for cancer
- Procedure type: Type C

### Category 3 - Therapeutic Procedures

#### Group T3 – Therapeutic Nuclear Medicine

##### Subgroup 2 – Theranostics

16055

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: \$8,000.00 Benefit: 85%: \$7,897.60\*, 75%: \$6,000.00

- **Private Health Insurance Classification:**
- **Clinical category: Chemotherapy, radiotherapy and immunotherapy for cancer**
- Procedure type: Type C

**Note TN.3.2 – Definition of ‘disease progression’ for the continuation of 177Lutetium PSMA therapy (MBS Item 16055)**

Continuing 177Lutetium PSMA therapy (MBS Item 16055) should not be claimed if disease progression has occurred while receiving 177Lutetium PSMA for metastatic castrate-resistant prostate cancer.

Response assessment can be made by utilising diagnostic imaging modalities including, but not limited to, PSMA PET or LuPSMA SPECT, and/or other clinically relevant markers. For Item 16055, disease progression is defined as:

- a rise in PSA of >2ng/mL confirmed by two tests a minimum of two weeks apart, and/or
- evidence of new soft tissue or bone metastases on diagnostic imaging computed tomography as per established guidelines (such as the Response Evaluation Criteria in Solid Tumours (RECIST) criteria, as published by the European Organisation for Research and Treatment of Cancer available at [www.eortc.org](http://www.eortc.org), or the Response Evaluation Criteria in PSMA-Imaging (RECIP) Criteria, available at [www.recip-criteria.com](http://www.recip-criteria.com)).

Please note that the information provided is a general guide only. It is ultimately the responsibility of treating practitioners to use their professional judgment to determine the most clinically appropriate services to provide, and then to ensure that any services billed to Medicare fully meet the eligibility requirements outlined in the legislation.

This factsheet is current as of the Last updated date shown above and does not account for MBS changes since that date.