Health Insurance (Section 3C - Lutetium PSMA Treatment) Determination 2025

I, Mary Warner, delegate of the Minister for Health and Aged Care, make the following Determination.

Dated 30 April 2025

Mary Warner
Assistant Secretary
Diagnostic Imaging and Pathology Branch
Medicare Benefits and Digital Health Division
Health Resourcing Group
Department of Health and Aged Care

Contents

1 Name

This instrument is the *Health Insurance (Section 3C – Lutetium PSMA Treatment) Determination 2025*.

2 Commencement

(1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information		
Column 1	**Column 2**	**Column 3**
Provisions	**Commencement**	**Date/Details**
1. The whole of this instrument	1 July 2025.	1 July 2025

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

(2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

This instrument is made under subsection 3C(1) of the *Health Insurance Act 1973.*

4 Definitions

(1) In this instrument:

Act means the *Health Insurance Act 1973*.

disease progression means either or both:

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

(b) 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 criteria, as published by the European Organisation for Research and Treatment of Cancer, or the Response Evaluation Criteria in PSMA-Imaging Criteria.

PET means positron emission tomography.

PSA means prostate-specific antigen

PSMA means prostate specific membrane antigen

nuclear medicine credentialled specialist means a specialist or consultant physician whose name is included in a register, given to the Chief Executive Medicare by the JNMCAC, of participants in the Joint Nuclear Medicine Specialist Credentialling Program of the JNMCAC.

relevant provisions means all provisions, of the Act and regulations made under the Act, and the *National Health Act 1953* and regulations made under the *National Health Act 1953*, relating to medical services, professional services or items.

relevant service means a health service, as defined in subsection 3C(8) of the Act, that is specified in a Schedule.

report means a report prepared by a medical practitioner.

(R) has the meaning given by clause 1.2.15 of the diagnostic imaging services table.

Schedule means a Schedule to this instrument.

SPECT means single-photon emission computed tomography.

SUV means standardised uptake value.

Note: The following terms are defined in subsection 3(1) of the Act:

- clinically relevant service
- diagnostic imaging services table
- general medical services table
- item
- professional service

(2) Unless the contrary intention appears, a reference in this instrument to a provision of the Act or the *National Health Act 1953* or regulations made under the Act or under the *National Health Act 1953* as applied, adopted or incorporated in relation to specifying a matter is a reference to those provisions as in force from time to time and any other reference to provisions of an Act or regulations is a reference to those provisions as in force from time to time.

5 Treatment of relevant services

For subsection 3C(1) of the Act, a relevant service, provided in accordance with this instrument and as a clinically relevant service, is to be treated, for the relevant provisions, as if:

(a) it were both a professional service and a medical service; and

(b) there were an item in the general medical services table or diagnostic imaging services table that:

(i) related to the service; and

(ii) specified for the service a fee in relation to each State, being the fee specified in the Schedule in relation to the service.

6 Application of provisions of the General Medical Services Table

Clause 5.4.1 shall have effect as if Items 16050 and 16055 of Schedule 1 of this Determination were also specified in clause 5.4.1 of the General Medical Services Table.

7 Application of provisions of the Diagnostic Imaging Services Table

Clause 2.4.6 shall have effect as if Item 61528 of Schedule 2 of this Determination was also specified in subclause 2.4.6 of the Diagnostic Imaging Services Table.

8 Limitation of item 61528

Item 61528 does not apply unless:

(a) the patient was referred by a specialist or consultant physician; and

(b) the service is provided by a nuclear medicine credentialled specialist.

9 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1 – General medical services

Category 3 – Therapeutic Procedures		
GroupT3 -Therapeutic Nuclear Medicine		
Column 1	**Column 2**	**Column 3**
Item	**Description**	**Fee ($)**
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.	8,000.00
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.	8,000.00

Schedule 2 – Diagnostic imaging services

Category 5 – Diagnostic Imaging Services

Group I4 – Nuclear Medicine Imaging

Subgroup 2 – PET

Column 1 Item	Column 2 Description	Column 3 Fee ($)
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.)	1,300.00