

## EXPLANATORY STATEMENT

### *Health Insurance Act 1973*

#### *Health Insurance (Section 3C – Lutetium PSMA Treatment) Amendment Determination 2025*

Subsection 3C(1) of the *Health Insurance Act 1973* (the Act) provides that the Minister may, by legislative instrument, determine that a health service not specified in an item in the general medical services table (the GMST) shall, in specified circumstances and for specified statutory provisions, be treated as if it were specified in the GMST.

The GMST is set out in the regulations made under subsection 4(1) of the Act. The most recent version of the regulations is the *Health Insurance (General Medical Services Table) Regulations 2021*.

This instrument relies on subsection 33(3) of the *Acts Interpretation Act 1901* (AIA). Subsection 33(3) of the AIA provides that where an Act confers a power to make, grant or issue any instrument of a legislative or administrative character (including rules, regulations or by-laws), the power shall be construed as including a power exercisable in the like manner and subject to the like conditions (if any) to repeal, rescind, revoke, amend, or vary any such instrument.

### **Purpose**

The purpose of the *Health Insurance (Section 3C – Lutetium PSMA Treatment) Amendment Determination 2025* (Amendment Determination) is to make an administrative amendment to the *Health Insurance (Section 3C – Lutetium PSMA Treatment) Determination 2025* (Principal Determination). The Principal Determination introduces new Medicare Benefits Schedule (MBS) items 16050 and 16055 for the treatment of progressive or symptomatic metastatic castrate resistant prostate cancer, where prior treatment has failed. The Amendment Determination amends the Principal Determination to move MBS items 16050 and 16055 to new ‘Subgroup 2 – Theranostics’ of ‘Group T3 – Therapeutic Nuclear Medicine’ of the MBS. This will provide further distinction between the new MBS items and the existing MBS items within ‘Group T3 – Therapeutic Nuclear Medicine’.

### **Consultation**

Consultation was not undertaken for this instrument as the amendment is administrative in nature.

The Amendment Determination is a legislative instrument for the purposes of the *Legislation Act 2003*.

The Amendment Determination will commence immediately after the commencement of Principal Determination.

Details of the Amendment Determination are set out in the Attachment.

Authority: Subsection 3C(1) of the  
*Health Insurance Act 1973*

## ATTACHMENT

**Details of the *Health Insurance (Section 3C – Lutetium PSMA Treatment) Amendment Determination 2025* (Amendment Determination)**

Section 1 – Name

Section 1 provides for the instrument to be referred to as the *Health Insurance (Section 3C – Lutetium PSMA Treatment) Amendment Determination 2025* (Amendment Determination).

Section 2 – Commencement

Section 2 provides for the Amendment Determination to commence immediately after the commencement of the *Health Insurance (Section 3C – Lutetium PSMA Treatment) Determination 2025* (Principal Determination).

Section 3 – Authority

Section 3 provides that the Amendment Determination is made under subsection 3C(1) of the *Health Insurance Act 1973*.

Section 4 – Schedules

Section 4 provides that each instrument that is specified in a Schedule to the Amendment Determination is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to the Amendment Determination has effect according to its terms.

Schedule 1—Amendments

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

**Item 1** repeals and substitutes the Schedule 1 table of the *Health Insurance (Section 3C – Lutetium PSMA Treatment) Determination 2025* to insert ‘Subgroup 2 – Theranostics’ in ‘Group T3 – Therapeutic Nuclear Medicine’ of the Medicare Benefits Schedule.

## Statement of Compatibility with Human Rights

*Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011*

*Health Insurance (Section 3C – Lutetium PSMA Treatment) Amendment Determination 2025*

This instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

### Overview of the Determination

The purpose of the *Health Insurance (Section 3C – Lutetium PSMA Treatment) Amendment Determination 2025* (Amendment Determination) is to make administrative amendments to the *Health Insurance (Section 3C – Lutetium PSMA Treatment) Determination 2025* (Principal Determination).

The Principal Determination introduces new Medicare Benefits Schedule (MBS) items 16050 and 16055 for the treatment of progressive or symptomatic metastatic castrate resistant prostate cancer, where prior treatment has failed. The Amendment Determination amends the Principal Determination to move MBS items 16050 and 16055 to new ‘Subgroup 2 – Theranostics’ of ‘Group T3 – Therapeutic Nuclear Medicine’ of the MBS. This will provide further distinction between the new MBS items and the existing MBS items within ‘Group T3 – Therapeutic Nuclear Medicine’.

### Human rights implications

This instrument engages Articles 9 and 12 of the International Covenant on Economic Social and Cultural Rights (ICESCR), specifically the rights to health and social security.

#### *The Right to Health*

The right to the enjoyment of the highest attainable standard of physical and mental health is contained in Article 12(1) of the ICESCR. The UN Committee on Economic Social and Cultural Rights (the Committee) has stated that the right to health is not a right for each individual to be healthy, but is a right to a system of health protection which provides equality of opportunity for people to enjoy the highest attainable level of health.

The Committee reports that the ‘*highest attainable standard of health*’ takes into account the country’s available resources. This right may be understood as a right of access to a variety of public health and health care facilities, goods, services, programs, and conditions necessary for the realisation of the highest attainable standard of health.

#### *The Right to Social Security*

The right to social security is contained in Article 9 of the ICESCR. It requires that a country must, within its maximum available resources, ensure access to a social security scheme that provides a minimum essential level of benefits to all individuals and families that will enable them to acquire at least essential health care. Countries are obliged to demonstrate that every effort has been made to use all resources that are at their disposal in an effort to satisfy, as a matter of priority, this minimum obligation.

The Committee reports that there is a strong presumption that retrogressive measures taken in relation to the right to social security are prohibited under ICESCR. In this context, a retrogressive measure would be one taken without adequate justification that had the effect of reducing existing levels of social security benefits, or of denying benefits to persons or groups

previously entitled to them. However, it is legitimate for a Government to re-direct its limited resources in ways that it considers to be more effective at meeting the general health needs of all society, particularly the needs of the more disadvantaged members of society.

*The right of equality and non-discrimination*

The rights of equality and non-discrimination are contained in articles 2, 16 and 26 of the International Covenant on Civil and Political Rights (ICCPR). Article 26 of the ICCPR requires that all persons are equal before the law, are entitled without any discrimination to the equal protection of the law and in this respect, the law shall prohibit any discrimination and guarantee to all persons equal and effective protection against discrimination on any ground such as race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status.

Analysis

This instrument does not affect the rights to health and social security and the right of equality and non-discrimination. This instrument makes administrative amendments to the Principal Determination from 1 July 2025 and there is no change to the Medicare arrangements for patients or health providers.

**Conclusion**

This instrument is compatible with human rights as it maintains the right to health and the right to social security and the right of equality and non-discrimination.

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