



Australian Government

Department of Health and Ageing

Ms Liz Adams
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Dear Ms Adams

Positron Emission Tomography (PET) Scanners in Australia

I refer to your email of 14 February 2009 regarding standards for PET scanners in Australia.

The funding and provision of PET services in Australia was assessed by the Medical Services Advisory Committee (MSAC) in 2000 and 2001, but there was insufficient evidence to recommend unrestricted public funding through the Medicare Benefits Schedule (MBS). The previous Government provided interim funding for the collection of data to further assess PET's effectiveness. As a result seven facilities were contracted to collect data which was used to inform MSAC about the effectiveness of PET for specific conditions.

MSAC's assessment of PET is continuing and is expected to be completed by the end of 2009. The findings of the review will put the Australian Government in a better position to decide how best to support further access to PET services for all Australians in the future.

PET services are funded in Australia through two legislative instruments (Determinations), grant arrangements and election or other government commitments:

- the Facilities Determination 2009 allows seven facilities which participated in the data collection project to access a comprehensive range of MBS PET items;
- the PET Determination 2008 (No.2) allows all other eligible PET facilities that meet the specified requirements listed in the Determination to access the MBS for generally available PET items. There are currently nine indications on the Determination with an additional 6 items expected to be added in May 2009. A copy of the latest Determination is attached for your information;
- grant funding arrangement to two facilities for PET services and research; and
- through election or other government commitments, the Government funds the establishment of PET facilities in a number of areas where access to PET services are limited.

In Australia, there are no impediments to either State/Territory Health Departments or an individual private provider establishing their own PET facilities. If a hospital was to acquire a PET scanner and meet the required criteria, it too would be eligible to access Medicare funding for certain Medicare-eligible PET services.

There are currently 17 PET scanners operating out of 14 locations in Australia .. In 2007-08, Medicare funded over 17,000 PET scans at a cost of over \$15.8 million.

For further information, I have provided the following path to the Department of Health and Ageing's Medicare Benefits webpage. This provides more information on how the Australian Government pays Medicare Benefits to assist consumers with the costs of medical, optometrical and some dental surgical services.

<http://www.health.gov.au/internet/main/publishing.nsf/Content/health-medicarebenefits-index.htm>

I trust that this information is of assistance to you. Should you require further information I can be contacted on +61 2 6289 7315 or by email mary.warner@health.gov.au.

Yours sincerely



Mary Warner
Director
Diagnostic Imaging Section

23 February 2009



Health Insurance (Positron Emission Tomography) Determination 2008 (No.2).

I, NICOLA ROXON, Minister for Health and Ageing, make this Determination under subsection 3C(1) of the *Health Insurance Act 1973*.

Dated 10th NOVEMBER 2008

A handwritten signature in black ink, appearing to read 'Nicola Roxon', written over a horizontal line.

NICOLA ROXON
Minister for Health and Ageing

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1. Name of Determination

This Determination is the *Health Insurance (Positron Emission Tomography) Determination 2008 (No. 2)*.

2. Commencement and term

This Determination commences on 1 December 2008 and shall remain in force until midnight on 30 June 2010.

3. Revocation of *Health Insurance (Positron Emission Tomography) Determination 2008*

This Determination revokes *Health Insurance (Positron Emission Tomography) Determination 2008*.

4. Interpretation

(1) In this Determination:

accredited site is one that is accredited by ANZAPNM as a site for advanced training in PET.

Act means the *Health Insurance Act 1973*.

ANZAPNM means the Australian and New Zealand Association of Physicians in Nuclear Medicine Inc, a body incorporated under the *Associations Incorporation Act 1987 (WA)*.

authorised officer means, in relation to functions under this Determination:

- (a) an employee of Medicare Australia authorised by the CEO of Medicare Australia; and
- (b) an APS employee (within the meaning of the *Public Service Act 1999*) authorised by the Secretary.

comprehensive facility means:

- (a) a building or part of a building; or
- (b) buildings, where public access between the buildings is by way of a covered pedestrian walkway;

where each of the following services is provided (whether or not other services are also provided):

- (i) PET;
- (ii) computed tomography;
- (iii) x-ray;
- (iv) diagnostic ultrasound;
- (v) medical oncology;
- (vi) surgical oncology;
- (vii) radiation oncology; and
- (viii) neurology.

FDG means ¹⁸F-fluorodeoxyglucose.

PET means positron emission tomography.

quarter means a period of three months beginning on 1 January, 1 April, 1 July or 1 October of any year.

RACP means the Royal Australasian College of Physicians (ACN 000 039 047).

RANZCR means the Royal Australian and New Zealand College of Radiologists (ACN 000 029 863).

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

throughput requirement has the meaning given by subsection 5(4).

Note Unless the contrary intention appears, expressions used in this determination have the same meanings as in the Act—see section 13 of the *Legislative Instruments Act 2003*.

- (2) Unless the contrary intention appears, in this Determination a reference to a provision of the Act or regulations made under the Act 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. Circumstances where this Determination applies

- (1) This Determination applies only in the following circumstances:

- (a) where the relevant service is rendered:

- (i) pursuant to a written request made by a specialist or a consultant physician who determined that the service was necessary and whose patient the person was; and

Note This circumstance mirrors the requirement in paragraph 16B(1)(b) of the Act that, for a medicare benefit to be payable in respect of an R-type diagnostic imaging service, the service must be rendered pursuant to a written request, but limits which practitioners may request a relevant service

- (ii) by or under the personal supervision of:

(A) a credentialed specialist referred to in subsection (2); or

(B) a practitioner possessing the qualifications and experience prescribed in subsection (2A); and

- (iii) at an accredited site in a comprehensive facility; and

- (iv) using equipment that meets each of the standards specified by ANZAPNM as referred to in subsection (3); and

- (b) the owner or operator of the equipment used to provide the relevant services has not been given written notice by an authorised officer that the equipment fails to meet the throughput requirement referred to in subsection (4) and that notice remains in effect; and

- (c) if Medicare Australia has given written notice to the owner or operator of the equipment used to provide the relevant service that it

requires a statutory declaration to be provided in relation to circumstances referred to in this section, the owner or operator of the equipment has provided a statutory declaration to Medicare Australia in the timeframe specified in the notice; and

- (d) if the circumstances declared in a statutory declaration referred to in paragraph (c) have changed, the owner or operator has given Medicare Australia written notice of the change as soon as the changed circumstances have come to the attention of the owner or operator, as the case may be.

- (2) A *credentialed specialist* is a specialist or a consultant physician (not being the requesting practitioner mentioned in subparagraph (1)(a)(i)) credentialed under the 'Joint Nuclear Medicine Specialist Credentialing Program for the Recognition of the Credentials of Nuclear Medicine Specialists for Positron Emission Tomography' overseen by the Joint Nuclear Medicine Credentialing and Accreditation Committee established from time to time by the RACP and the RANZCR.

(2A) For subparagraph (1)(a)(ii), the following qualifications and experience are prescribed:

- (a) the practitioner (not being the requesting practitioner mentioned in subparagraph (1)(a)(i)) is a Fellow of the RACP or Fellow of the RANZCR;
- (b) the practitioner has reported 400 or more studies forming part of PET services in respect of which a Medicare benefit was payable; and
- (c) the practitioner holds a current licence from the relevant State radiation licensing body to prescribe and administer the intended PET radiopharmaceuticals to humans.

(3) For subparagraph (1)(a)(iv), the standards specified by ANZAPNM are the:

- (a) *Interim Recommendations for PET Accreditation (Technical Aspects)* dated 16 May 2001 and issued by the Australian and New Zealand Society of Nuclear Medicine (a body incorporated under the *Associations Incorporation Act 1984* (NSW)), but not including the NEMA NU 2-2000 standard referred to in that document; and
- (b) NEMA NU 2-2001 standard published on 20 June 2001 and issued by the National Electrical Manufacturers Association, a non-stock corporation organised under the General Corporation Law of the State of Delaware (United States of America),

being those documents in existence immediately before this Determination commences.

- (4) For paragraph (1)(b), the throughput requirement is that each piece of PET equipment located at the accredited site is used to render at least 20 relevant services each quarter following the quarter when the equipment is first used to render a relevant service.
- (5) For paragraph (1)(b), an authorised officer may, by written notice to the owner or operator of the equipment, revoke a notice referred to in that

paragraph (1)(b) if satisfied that the equipment will meet the throughput requirement in future, having regard to action taken by the owner or operator (after the notice was given) aimed at meeting that requirement.

6. Treatment of certain positron emission tomography services

A relevant service shall be treated for the purposes of the provisions of the Act and of regulations made under the Act and the provisions of the *National Health Act 1953* and of regulations made under the *National Health Act 1953*

that make provision in respect of professional services or medical services as if:

- (a) it was both a professional service and a medical service; and
- (b) there was an item of an R-type diagnostic imaging service in the diagnostic imaging services table that:
 - (i) related to the relevant service; and
 - (ii) specified in respect of the service a fee in relation to a State, being the fee specified in the Schedule in relation to the State specified.

7. Certain positron emission tomography services—items and specifications etc

Each of the following provisions:

- (a) subrule 3(1) of Part 2 of Schedule 1 of the *Health Insurance (Diagnostic Imaging Services Table) Regulations 2007* or regulations that replace them;
- (b) any regulation made under the Act that identifies an item in the diagnostic imaging services table as an R-type diagnostic imaging service;
- (c) regulation 13 of the *Health Insurance Regulations 1975*, so far as it relates to professional services generally or diagnostic imaging services specifically,

shall have effect as if a relevant service, and the items that, by virtue of paragraph 6(b), relate to a relevant service, were also specified in the provision.

Schedule – Specified health services

Item	Health Service	Fee for all States
61523	Whole body FDG PET study, performed for evaluation of a solitary pulmonary nodule, where the lesion is considered unsuitable for transthoracic fine needle aspiration biopsy, or for which an attempt at pathological characterisation has failed. (R)	<i>\$953.00</i>
61529	Whole body FDG PET study, performed for the staging of proven non-small cell lung cancer, where curative surgery or radiotherapy is planned. (R)	<i>\$953.00</i>
61541	Whole body FDG PET study, following initial therapy, performed for the evaluation of suspected residual, metastatic or recurrent colorectal carcinoma in patients considered suitable for active therapy.	<i>\$953.00</i>
61544	Whole body FDG PET study, following initial therapy, performed for the evaluation of suspected residual, metastatic or recurrent colorectal carcinoma in patients considered suitable for active therapy, with catheterisation of the bladder.	<i>\$975.00</i>
61553	Whole body FDG PET study, following initial therapy, performed for the evaluation of suspected metastatic or recurrent malignant melanoma in patients considered suitable for active therapy.	<i>\$999.00</i>
61556	Whole body FDG PET study, following initial therapy, performed for the evaluation of suspected metastatic or recurrent malignant melanoma in patients considered suitable for active therapy, with catheterisation of the bladder.	<i>\$1021.00</i>
61559	FDG PET study of the brain, performed for the evaluation of refractory epilepsy, which is being evaluated for surgery. (R)	<i>\$918.00</i>
61565	Whole body FDG PET study, following initial therapy, performed for the evaluation of suspected residual, metastatic or recurrent ovarian carcinoma in patients considered suitable for active therapy.	<i>\$953.00</i>
61568	Whole body FDG PET study, following initial therapy, performed for the evaluation of suspected residual, metastatic or recurrent ovarian carcinoma in patients considered suitable for active therapy with curative intent, with catheterisation of the bladder.	<i>\$975.00</i>

Note Subsection 3C(7) of the Act deems an internal territory to form part of the State of New South Wales.