



# **Medicare Benefits Schedule Review Taskforce**

**Report from the  
Diagnostic Imaging  
Clinical Committee –  
Nuclear Medicine**



## Important note

The views and recommendations in this review report from the clinical committee have been released for the purpose of seeking the views of stakeholders.

This report does not constitute the final position on these items, which is subject to:

- Stakeholder feedback;

Then

- Consideration by the MBS Review Taskforce;

Then *if endorsed*

- Consideration by the Minister for Health; and
- Government.

### Confidentiality of comments:

If you want your feedback to remain confidential please mark it as such. It is important to be aware that confidential feedback may still be subject to access under freedom of information law.



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# 1. Executive summary

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The Medicare Benefits Schedule (MBS) Review Taskforce (the Taskforce) is undertaking a program of work that considers how more than 5,700 items on the MBS can be aligned with contemporary clinical evidence and practice and improve health outcomes for patients. The Taskforce will also seek to identify any services that may be unnecessary, outdated or potentially unsafe.

The Taskforce is committed to providing recommendations to the Minister for Health (the Minister) that will allow the MBS to deliver on each of these four key goals:

- Affordable and universal access
- Best practice health services
- Value for the individual patient
- Value for the health system.

The Taskforce has endorsed a methodology whereby the necessary clinical review of MBS items is undertaken by clinical committees and working groups.

The Diagnostic Imaging Clinical Committee (the Committee) was established in 2015 to make recommendations to the Taskforce on the review of MBS items in its area of responsibility, based on rapid evidence review and clinical expertise.

The recommendations from the clinical committees are released for stakeholder consultation. The clinical committees consider feedback from stakeholders then provide recommendations to the Taskforce in a Review Report. The Taskforce considers the Review Reports from clinical committees and stakeholder feedback before making recommendations to the Minister for consideration by Government.

## 1.1 Key recommendations

An outline of the most important recommendations made during this review is given below. The complete recommendations (and the accompanying rationales) for all items can be found in Section 4. Recommendations developed for referral to other committees are presented in Section 5.

All recommendations are summarised in plain English in Appendix A. A complete list of items, including the nature of the recommendations and the page number for each recommendation, can be found in Appendices B and C (in table summary form).





## Recommendations for consultation

The Committee's recommendations for stakeholder consultation are that:

- △ 17 items should be deleted from the MBS;
- △ 49 items should be changed; and
- △ 41 items should remain unchanged.

The Committee has proposed **eight** new items; with **six** expected to be referred to the Medicare Services Advisory Committee (MSAC). **Two of these items are expected to be referred to the Therapeutic Goods Administration (TGA) for addition of radiopharmaceuticals to the Australian Register of Therapeutic Goods (ARTG) prior to referral to MSAC.**

These changes focus on encouraging best practice, modernising the MBS to reflect contemporary practice, and ensuring that MBS services provide value for the patient and the healthcare system. These changes focus on encouraging best practice, modernising the MBS to reflect contemporary practice, and ensuring that MBS services provide value for the patient and the healthcare system.

Significant recommendations are summarised below.

- △ **Cardiac items** (Section 4.1 of the report) To restructure and rationalise the nuclear medicine cardiac items, by removing planar imaging items, adding the fee for the exercise ECG item to relevant stress myocardial perfusion scan (MPS) items, and creating separate items for rest imaging and stress imaging to remove any financial incentive to perform stress and rest studies over separate days.
- △ **MBS Positron Emission Tomography (PET) items** (Section 4.4 of the report). Expand the indications (cancer types) for MBS PET services to include all fluorodeoxyglucose (FDG)-avid solid tumours and consolidate all MBS PET items into four items: covering diagnosis, staging, response assessment and recurrence (re-staging) for all FDG-avid tumours.
- △ **Therapeutic nuclear medicine items** (Section 4.5 of the report). To modernise this part of the Schedule to align with contemporary practice, by recommending the transfer of funding for therapeutic radionuclides from the MBS to the Pharmaceutical Benefits Scheme (PBS), increasing fees, pursuing listing of radium-223, and Australian registration of therapeutic nuclear medicine items on the clinical horizon.

## Recommendations for referral to other committees

The Committee's recommendations to be referred to MSAC for their consideration are:

- △ **Item 35404—Dosimetry, handling and injection of SIR-spheres** (Section 4.6). The Committee recommends expanding the patient population for this item to include other cancer types and in combination with other chemotherapy regimens for which there is clinical evidence of effectiveness.
- △ Restructuring of MBS PET items as discussed in 1.3.1 above.



## 1.2 Consumer impact

The Committee believes it is important to find out from consumers if they will be helped or disadvantaged by the recommendations—and how, and why. After public consultation the Committee will assess the advice from consumers and decide whether any changes are needed to the recommendations.

The Committee will then send the recommendations to the Taskforce. The Taskforce will consider the recommendations as well as the information provided by consumers to make sure all the important concerns are addressed. The Taskforce will then provide the recommendation to government.

- △ The Committee brought together practitioners with experience in, and commitment to, the care of people with clinical diseases, to examine how well the description of Medicare items match current clinical practice and meet the needs of Australians.
- △ There is a list of key recommendations, written in plain English, in Appendix A—Summary for consumers.
- △ Changes have been recommended for some items that are no longer up to date. Some items are no longer used, and some should not be used because clinical best practice has changed since they were originally described. These items have been recommended for deletion.
- △ When considering whether to recommend a deletion, the Committee was mindful that Australia is a large country with considerable differences in medical services offered in large urban centres such as Sydney and in smaller regional and remote centres. Therefore, a national view, noting the impact in rural areas, was employed by the Committee when any recommendations for obsolescence were made.
- △ The recommendation from the Committee with the widest-ranging consumer impact is its recommendation to overhaul the MBS PET items (Section 4.4). Under the current Schedule, many patients with FDG-avid cancers such as, pancreatic cancer, thyroid cancer, gastric cancer and breast cancer, are ineligible for MBS-funded PET scans, creating inequities in access to services for Australians, depending on the particular cancer diagnosis [2]. If implemented, the Committee's recommendation would offer greater equity of access to Australian consumers affected by cancer and bring Australia's PET funding indications into line with those in other developed countries, such as the USA and the UK.



## 2. About the Medicare Benefits Schedule (MBS) Review

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### 2.1 Medicare and the MBS

#### 2.1.1 What is Medicare?

Medicare is Australia's universal health scheme that enables all Australian residents (and some overseas visitors) to have access to a wide range of health services and medicines at little or no cost.

Introduced in 1984, Medicare has three components:

- free public hospital services for public patients
- subsidised drugs covered by the Pharmaceutical Benefits Scheme (PBS)
- subsidised health professional services listed on the MBS.

### 2.2 What is the MBS?

The MBS is a listing of the health professional services subsidised by the Australian Government. There are more than 5,700 MBS items that provide benefits to patients for a comprehensive range of services, including consultations, diagnostic tests and operations.

### 2.3 What is the MBS Review Taskforce?

The Government established the Taskforce as an advisory body to review all of the 5,700 MBS items to ensure they are aligned with contemporary clinical evidence and practice and improve health outcomes for patients. The Taskforce will also modernise the MBS by identifying any services that may be unnecessary, outdated or potentially unsafe. The Review is clinician-led, and there are no targets for savings attached to the Review.

#### 2.3.1 What are the goals of the Taskforce?

The Taskforce is committed to providing recommendations to the Minister that will allow the MBS to deliver on each of these four key goals:

- **Affordable and universal access**—the evidence demonstrates that the MBS supports very good access to primary care services for most Australians, particularly in urban Australia. However, despite increases in the specialist workforce over the last decade, access to many specialist services remains problematic, with some rural patients being particularly under-served.



- **Best practice health services**—one of the core objectives of the Review is to modernise the MBS, ensuring that individual items and their descriptors are consistent with contemporary best practice and the evidence base when possible. Although the Medical Services Advisory Committee (MSAC) plays a crucial role in thoroughly evaluating new services, the vast majority of existing MBS items pre-date this process and have never been reviewed.
- **Value for the individual patient**—another core objective of the Review is to have an MBS that supports the delivery of services that are appropriate to the patient’s needs, provide real clinical value and do not expose the patient to unnecessary risk or expense.
- **Value for the health system**—achieving the above elements of the vision will go a long way to achieving improved value for the health system overall. Reducing the volume of services that provide little or no clinical benefit will enable resources to be redirected to new and existing services that have proven benefit and are underused, particularly for patients who cannot readily access those services currently.

## 2.4 The Taskforce’s approach

The Taskforce is reviewing existing MBS items, with a primary focus on ensuring that individual items and usage meet the definition of best practice. Within the Taskforce’s brief, there is considerable scope to review and provide advice on all aspects that would contribute to a modern, transparent and responsive system. This includes not only making recommendations about adding new items or services to the MBS, but also about an MBS structure that could better accommodate changing health service models.

The Taskforce has made a conscious decision to be ambitious in its approach, and to seize this unique opportunity to recommend changes to modernise the MBS at all levels, from the clinical detail of individual items, to administrative rules and mechanisms, to structural, whole-of-MBS issues. The Taskforce will also develop a mechanism for an ongoing review of the MBS once the current review has concluded.

As the MBS Review is clinician-led, the Taskforce decided that clinical committees should conduct the detailed review of MBS items. The committees are broad-based in their membership, and members have been appointed in an individual capacity, rather than as representatives of any organisation.

The Taskforce asked the committees to review MBS items using a framework based on Professor Adam Elshaug’s appropriate use criteria (1) . The framework consists of seven steps:

1. Develop an initial fact base for all items under consideration, drawing on the relevant data and literature.



2. Identify items that are obsolete, are of questionable clinical value<sup>1</sup>, are misused<sup>2</sup> and/or pose a risk to patient safety. This step includes prioritising items as “priority 1”, “priority 2”, or “priority 3”, using a prioritisation methodology (described in more detail below).
3. Identify any issues, develop hypotheses for recommendations and create a work plan (including establishing working groups, when required) to arrive at recommendations for each item.
4. Gather further data, clinical guidelines and relevant literature in order to make provisional recommendations and draft accompanying rationales, as per the work plan. This process begins with priority 1 items, continues with priority 2 items and concludes with priority 3 items. This step also involves consultation with relevant stakeholders within the committee, working groups, and relevant colleagues or Colleges. For complex cases, full appropriate use criteria were developed for the item’s explanatory notes.
5. Review the provisional recommendations and the accompanying rationales, and gather further evidence as required.
6. Finalise the recommendations in preparation for broader stakeholder consultation.
7. Incorporate feedback gathered during stakeholder consultation and finalise the Review Report, which provides recommendations for the Taskforce.

All MBS items will be reviewed during the course of the MBS Review. However, given the breadth of and timeframe for the Review, each clinical committee has to develop a work plan and assign priorities, keeping in mind the objectives of the Review. Committees use a robust prioritisation methodology to focus their attention and resources on the most important items requiring review. This was determined based on a combination of two standard metrics, derived from the appropriate use criteria:

- Service volume.
- The likelihood that the item needed to be revised, determined by indicators such as identified safety concerns, geographic or temporal variation, delivery irregularity, the

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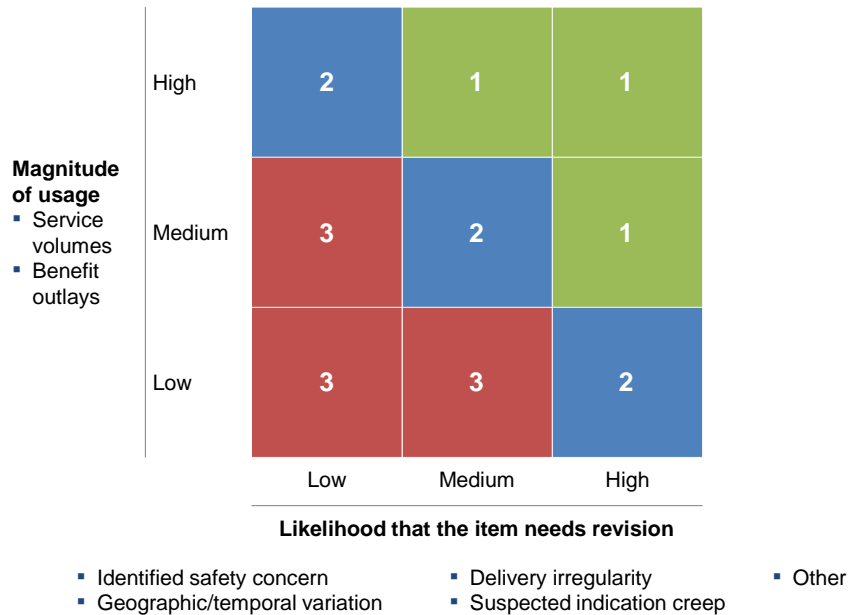
<sup>1</sup> The use of an intervention that evidence suggests confers no or very little benefit on patients; or where the risk of harm exceeds the likely benefit; or, more broadly, where the added costs of the intervention do not provide proportional added benefits.

<sup>2</sup> The use of MBS services for purposes other than those intended. This includes a range of behaviours, from failing to adhere to particular item descriptors or rules through to deliberate fraud.



potential misuse of indications or other concerns raised by the clinical committee (such as inappropriate co-claiming).

**Figure 1: Prioritisation matrix**



For each item, these two metrics were ranked high, medium or low. These rankings were then combined to generate a priority ranking ranging from one to three (where priority 1 items are the highest priority and priority 3 items are the lowest priority for review), using a prioritisation matrix (Figure 1). Clinical committees use this priority ranking to organise their review of item numbers and apportion the amount of time spent on each item.



## 3. About the Diagnostic Imaging Clinical Committee

The Committee is part of the first tranche of clinical committees. It was established in 2015 to make recommendations to the Taskforce on the review of MBS items within its remit, based on rapid evidence review and clinical expertise.

### 3.1 Diagnostic Imaging Clinical Committee members

The Committee consists of 12 members, whose names, positions/organisations and declared conflicts of interest are listed in Table 1.

**Table 1: Diagnostic Imaging Clinical Committee members**

Name	Position/organisation	Declared conflict of interest
Dr David Brazier (Chair)	Radiologist, Royal North Shore Hospital	User of MBS services Provider of MBS services
Professor Alexander Pitman	Director of Nuclear Medicine and PET, Lake Imaging; Adjunct Professor, Medical Imaging, University of Notre Dame	User of MBS services Provider of MBS services
Dr William Macdonald	Head, Nuclear Medicine, Fiona Stanley Hospital and Royal Perth Hospital; Past President, Australasian Association of Nuclear Medicine Specialists	User of MBS services Provider of MBS services
Dr Richard Ussher	Director of Training, Radiology, Ballarat Health Services; Director, Grampians BreastScreen	User of MBS services Provider of MBS services
Clinical Associate Professor Sanjay Jeganathan	Managing Partner & Lead Radiologist, Perth Radiological Clinic, Bentley Hospital; Consultant Radiologist, Fiona Stanley Hospital; Councillor, Faculty of Clinical Radiology, Royal Australian and New Zealand College of Radiologists	User of MBS services Provider of MBS services
Dr Michael Jones*	Radiologist, PRP Diagnostic Imaging	User of MBS services Provider of MBS services
Dr Walid Jammal	Clinical Lecturer, Faculty of Medicine, University of Sydney; Conjoint Senior Lecturer,	User of MBS services



	School of Medicine, University of Western Sydney; Private practice	Provider of MBS services
Associate Professor Rachael Moorin	Associate Professor, Health Policy & Health Economics, School of Public Health, Curtin University	User of MBS services
Professor Jenny Doust*	Professor of Clinical Epidemiology, Centre for Research in Evidence Based Practice, Bond University; General Practitioner	User of MBS services
Ms Geraldine Roberston	Consumer Representative, Consumers Health Forum & Breast Cancer Network Australia	User of MBS services
Dr Matthew Andrews	MBS Review Taskforce (ex-officio)	User of MBS services Provider of MBS services
Dr Bastian Seidel*	Director, Huon Valley Health Centre; Clinical Professor, Faculty of Health, University of Tasmania; Chair, Tasmanian Faculty, The Royal Australian College of General Practitioners; General Practitioner, Private practice	User of MBS services

\*Professor Doust, Dr Jones and Dr Seidel resigned from the Committee prior to the conclusion of this review.

## 3.2 Nuclear Medicine Working Group

The Nuclear Medicine Working Group (NMWG) is one of six clinical working groups that have been established to support the work of the Committee. It was established to review nuclear medicine items and make recommendations to the Committee based on rapid evidence review and clinical expertise.

The NMWG consists of nine members, whose names, positions, organisations and declared conflicts of interest are listed in Table 2 below.

**Table 2: Nuclear Medicine Working Group members**

Name	Position/organisation	Declared conflict of interest
Dr William Macdonald	Head, Nuclear Medicine, Fiona Stanley Hospital and Royal Perth Hospital; Past President, Australasian Association of Nuclear Medicine Specialists	User of MBS services Provider of MBS services
Associate Professor Rachael Moorin	Associate Professor, Health Policy & Health Economics, School of Public Health, Curtin University	User of MBS services





Name	Position/organisation	Declared conflict of interest
Associate Professor Paul Roach	Director, Nuclear Medicine, Royal North Shore Hospital; Clinical Associate Professor, University of Sydney	User of MBS services
Professor Hugh Dixon	Senior Staff Specialist in Gastroenterology, Nuclear Medicine & Ultrasound, Bankstown Lidcombe Hospital; Conjoint Senior Lecturer, University of NSW	User of MBS services
Dr Emily Mackenzie	Staff Specialist, Diabetes and Endocrinology & Nuclear Medicine, Princess Alexandra Hospital	User of MBS services
Dr Girolamo (Jerry) Moschilla	Radiologist, SKG Radiology & Fiona Stanley and Royal Perth Hospitals	User of MBS services
Professor Gillian Duchesne	Radiation Oncologist, Peter MacCallum Cancer Centre & Epworth Radiation Oncology	User of MBS services
Dr Frederick Khafagi	Clinical Director, Nuclear Medicine, The Prince Charles Hospital	User of MBS services
Professor Michael Feneley AM	Head, Cardiac Mechanics Laboratory. Director, Cardiology, St Vincent's Hospital. Professor, Department of Medicine, University of NSW	User of MBS services

### 3.3 Conflicts of interest

All members of the Taskforce, clinical committees and working groups are asked to declare any conflicts of interest at the start of their involvement and reminded to update their declarations periodically. A complete list of declared conflicts of interest can be viewed in Tables 1 and 2 above.

It is noted that the majority of the Committee members share a common conflict of interest in reviewing items that are a source of revenue for them (i.e. Committee members claim the items under review). This conflict is inherent in a clinician-led process, and having been acknowledged by the Committee and the Taskforce, it was agreed that this should not prevent a clinician from participating in the review.

### 3.4 Areas of responsibility of the Committee

Nuclear medicine is a medical specialty that involves the administration of a small amount of a radioactive medication (radiopharmaceutical) into the patient. Images are made from the ionising radiation emitted from the patient. While most commonly administered by intravenous injection, radiopharmaceuticals may also be administered by other methods [3].



Current nuclear medicine techniques include Positron Emission Tomography (PET) and Single Photon Emission Computed Tomography (SPECT). The Department of Health does not fund the use of radiopharmaceuticals used in nuclear medicine separately. Instead, under the MBS fee-for-service pricing structure, the cost of the radiopharmaceutical must be met from the MBS fee, along with the professional fee and other practice expenses.

For a nuclear medicine imaging service to be eligible under the MBS, the service must be performed by a specialist or consultant physician, or by a suitably qualified person acting on behalf of a specialist. The final report of the service must also be compiled by the specialist who performed the preliminary examination of the patient and administered the radiopharmaceutical [3].

The Committee was assigned 108 MBS nuclear medicine items to review. A complete list of these items can be found in Appendix A.

### 3.5 Summary of the Committee's review approach

The Committee reviewed 108 nuclear medicine items and developed the recommendations and rationales outlined in Section 4. The Committee was also asked to provide comment on the Cardiac Services Clinical Committee (CSCC) recommendations with respect to cardiac imaging.

The Review drew on various types of MBS data, including data on utilisation of items (services, benefits, patients, providers and growth rates); service provision (type of provider, geography of service provision); patients (demographics and services per patient); co-claiming or episodes of services (same-day claiming and claiming with specific items over time); and additional provider and patient-level data, when required. The review also drew on data presented in the relevant literature and clinical guidelines, all of which are referenced in the report.

An inclusive set of stakeholders is now engaged in consultation on the recommendations resulting from this process, which are outlined in this report. Following this period of consultation, the Committee will consider stakeholder feedback before finalising the recommendations and presenting them to the Taskforce. The Taskforce will consider the report and stakeholder feedback before making recommendations to the Minister for Health for consideration by the Government.



## 4. Recommendations

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The Committee reviewed 108 assigned nuclear medicine items and made recommendations based on evidence and clinical expertise, in consultation with relevant stakeholders. The item-level recommendations are described below. A summary list of recommendations can be found in Appendix A and the consumer summary table in Appendix C.

The Committee's recommendations are that 17 items should be deleted (and their services no longer provided under the MBS); 49 items should be changed; and 41 items should remain unchanged.

In addition to the above recommendations, the NMWG has recommended the deletion of all nuclear medicine NK items from the Schedule, in line with the recommendation from the Committee to abolish NK items across the entire diagnostic imaging table. An (NK) item must be claimed when the service is rendered using older equipment. For reference, the schedule fee for an (NK) item is approximately 50% of the schedule fee of its equivalent (K) item. The differential fees encourage service providers to upgrade and replace (as appropriate) aged equipment with the aim of improving the delivery of imaging services [4].

The changes focus on encouraging best practice, modernising the MBS to reflect contemporary practice, and ensuring that MBS services provide value for the patient and the healthcare system. Some of this can be achieved by:

- △ deleting items that are obsolete;
- △ consolidating or splitting items to reflect contemporary practice;
- △ modernising item descriptors to reflect best practice; and
- △ providing clinical guidance for appropriate use through explanatory notes.

The recommendations are presented by item groups, with the higher priority items to be discussed first.



## 1.1 Cardiac nuclear medicine items

Ten cardiac items were considered in the review. Many MBS cardiac nuclear medicine services are for stress or rest myocardial perfusion studies (MPS), or a combined study, whereby the patient undergoes two consecutive studies, one with exercise or pharmacological stress and the other at rest, for the evaluation of coronary artery disease. Planar techniques, which produce a 2-dimensional image, are rarely used any longer and have been superseded by 3-dimensional SPECT imaging, which uses a rotating camera system and tomographic reconstruction [5].

**Table 3: Introduction table for cardiac nuclear medicine items**

Item	Long item descriptor	Schedule fee	Services FY2014–15	5-year service change (CAGR)	Benefits FY2014–15
61302	SINGLE STRESS OR REST MYOCARDIAL PERFUSION STUDY - planar imaging. (R)	\$448.85	107	7.7%	\$44,849
61303	SINGLE STRESS OR REST MYOCARDIAL PERFUSION STUDY - with single photon emission tomography and with planar imaging when undertaken. (R)	\$565.30	6630	17.4%	\$3,484,260
61306	COMBINED STRESS AND REST, stress and re-injection or rest and redistribution myocardial perfusion study, including delayed imaging or re-injection protocol on a subsequent occasion - planar imaging. (R)	\$709.70	106	16.2%	\$70,282
61307	COMBINED STRESS AND REST, stress and re-injection or rest and redistribution myocardial perfusion study, including delayed imaging or re-injection protocol on a subsequent occasion - with single photon emission tomography and with planar imaging when undertaken. (R)	\$834.90	74,831	−0.7%	\$58,475,141
61310	MYOCARDIAL INFARCT-AVID-STUDY, with planar imaging and single photon emission tomography, OR planar imaging or single photon emission tomography. (R)	\$367.30	8	2.7%	\$2,598
61313	GATED CARDIAC BLOOD POOL STUDY, (equilibrium), with planar imaging and single	\$303.35	10,750	−0.3%	\$3,043,918



Item	Long item descriptor	Schedule fee	Services FY2014–15	5-year service change (CAGR)	Benefits FY2014–15
	photon emission tomography OR planar imaging or single photon emission tomography. (R)				
61314	GATED CARDIAC BLOOD POOL STUDY, and first pass blood flow or cardiac shunt study, with planar imaging and single photon emission tomography, OR planar imaging, or single photon emission tomography. (R)	\$420.00	1301	–2.9%	\$506,173
61316	GATED CARDIAC BLOOD POOL STUDY, with intervention, with planar imaging and single photon emission tomography, OR planar imaging, or single photon emission tomography. (R)	\$318.15	411	5.1%	\$148,442
61317	GATED CARDIAC BLOOD POOL STUDY, with intervention and first pass blood flow study or cardiac shunt study, with planar imaging and single photon emission tomography OR planar imaging, or single photon emission tomography. (R)	\$492.40	122	–2.1%	\$56,865
61320	CARDIAC FIRST PASS BLOOD FLOW STUDY OR CARDIAC SHUNT STUDY, not being a service to which another item in this Group applies. (R)	\$228.90	19	2.2%	\$4,064

### 1.1.1 Recommendation 1

The Committee recommended a restructuring and rationalisation of the nuclear medicine cardiac items, involving the following changes:

- △ Delete item 61302 from the Schedule.
- △ Amend the descriptor for item 61303 to remove reference to the type of imaging technology (see Table 4).
- △ Delete item 61306 from the Schedule.
- △ Amend the descriptor for item 61307 to remove reference to the type of imaging technology (see Table 4).
- △ Amend the descriptor for item 61310 to remove reference to imaging technique (planar vs SPECT).



- △ Amend item descriptor for item 61313 to remove reference to imaging technique (planar vs SPECT).
- △ Abolish items 61316, 61317 and 61320 and consolidate these item indications within item 61314.
- △ Amend the descriptor for item 61314 to remove reference to the imaging technology.
- △ Add the fee for the exercise ECG item (11712) to the relevant stress MPS items, in line with CSCC recommendations, with the separate co-claiming of stress ECG to be abolished.
- △ Create separate items for rest imaging and stress imaging (items 61303A and 61303B in Table 4) to remove any financial incentive to perform stress and rest studies over separate days, with the total fee for these items adding up to the fee for item 61307—the split to be one-third for rest (i.e. \$329.02) and two-thirds for stress (i.e. \$658.03), these fees increased from those in current Schedule to include the stress ECG component. See Table 4, below, for the proposed descriptors and fees.



Table 4: Proposed changes to cardiac nuclear medicine items

Item	Current descriptor	Proposed change/ Revised descriptor
61302	SINGLE STRESS OR REST MYOCARDIAL PERFUSION STUDY - planar imaging. (R)	Delete and incorporate into items 61303A and 61303B
61303	SINGLE STRESS OR REST MYOCARDIAL PERFUSION STUDY - with single photon emission tomography and with planar imaging when undertaken. (R)	<p>Item 61303A Single stress myocardial perfusion study, performed for:</p> <ul style="list-style-type: none"> <li>(a) Evaluation of symptoms possibly related to cardiac ischaemia</li> <li>(b) Assessment of functional severity of known CAD</li> <li>(c) Pre-operative assessment of a patient at intermediate or high risk of CAD</li> </ul> <p>Not claimable for (i) screening; or (ii) patients who are asymptomatic and have a normal cardiac examination; A myocardial perfusion study is claimable no more than once every 12 months in the absence of significant symptom evolution and/or revascularisation.</p> <p>Including:</p> <ul style="list-style-type: none"> <li>(a) Exercise or pharmacological stress; and</li> <li>(b) Multi-channel ECG monitoring and recording; and</li> <li>(b) The performance of the study as per current recommendations of the CSANZ.</li> </ul> <p>Fee: \$658.03</p> <p>Item 61303B Single rest myocardial perfusion study</p> <ul style="list-style-type: none"> <li>(a) Performed in conjunction with stress myocardial perfusion imaging (item 61303A) for: <ul style="list-style-type: none"> <li>(i) Evaluation of symptoms possibly related to cardiac ischaemia</li> <li>(ii) Assessment of functional severity of known CAD</li> <li>(iii) Pre-operative assessment of a patient at intermediate or high risk of CAD; or</li> </ul> </li> <li>(b) Performed for evaluation of myocardial perfusion and left ventricular function in patients with suspected cardiomyopathy</li> </ul> <p>Fee: \$329.02</p>
61306	COMBINED STRESS AND REST, stress and re-injection or rest and redistribution myocardial perfusion study, including delayed imaging or re-injection protocol on a subsequent occasion - planar imaging. (R)	Delete and incorporate into item 61307
61307	COMBINED STRESS AND REST, stress and re-injection or rest and redistribution myocardial perfusion study, including delayed imaging or re-injection protocol on a subsequent occasion - with single photon emission tomography and with planar imaging when undertaken. (R)	<p>Combined stress and rest, stress and re-injection or rest and redistribution myocardial perfusion study, including delayed imaging or re-injection protocol on a subsequent occasion - performed for:</p> <ul style="list-style-type: none"> <li>(a) Evaluation of symptoms possibly related to cardiac ischaemia</li> </ul>



Item	Current descriptor	Proposed change/ Revised descriptor
		<p>(b) Assessment of functional severity of known CAD</p> <p>(c) Pre-operative assessment of a patient at intermediate or high risk of CAD;</p> <p>Not claimable for (i) screening; or (ii) patients who are asymptomatic and have a normal cardiac examination. A myocardial perfusion study is claimable no more than once every 12 months in the absence of significant symptom evolution and/or revascularisation.</p> <p>Including:</p> <p>(a) Exercise or pharmacological stress; and</p> <p>(b) Multi-channel ECG monitoring and recording; and</p> <p>(c) The performance of the study as per current recommendations of the CSANZ.</p> <p>Fee: \$987.05</p>
61310	MYOCARDIAL INFARCT-AVID-STUDY, with planar imaging and single photon emission tomography, OR planar imaging or single photon emission tomography. (R)	MYOCARDIAL INFARCT-AVID-STUDY.
61313	GATED CARDIAC BLOOD POOL STUDY, (equilibrium), with planar imaging and single photon emission tomography OR planar imaging or single photon emission tomography. (R)	GATED CARDIAC BLOOD POOL STUDY, (equilibrium).
61314	GATED CARDIAC BLOOD POOL STUDY, and first pass blood flow or cardiac shunt study, with planar imaging and single photon emission tomography, OR planar imaging, or single photon emission tomography. (R)	GATED CARDIAC BLOOD POOL STUDY, including first pass blood flow or cardiac shunt study, or intervention study.
61316	GATED CARDIAC BLOOD POOL STUDY, with intervention, with planar imaging and single photon emission tomography, OR planar imaging, or single photon emission tomography. (R)	Delete item and consolidate indications in item 61314.
61317	GATED CARDIAC BLOOD POOL STUDY, with intervention and first pass blood flow study or cardiac shunt study, with planar imaging and single photon emission tomography OR planar imaging, or single photon emission tomography. (R)	Delete item and consolidate indications in item 61314.
61320	CARDIAC FIRST PASS BLOOD FLOW STUDY OR CARDIAC SHUNT STUDY, not being a service to which another item in this group applies. (R)	Delete item and consolidate indications in item 61314.

### 1.1.2 Rationale 1

The Committee's rationale for these recommendations is as follows:

- △ Planar imaging is largely superseded technology for cardiac imaging, replaced by SPECT in almost all cases [5]. For this reason and to simplify the Schedule, the separate planar imaging MBS items numbers should be deleted and consolidated within the relevant SPECT item numbers (61303, 61307, 61314), with the type of imaging technology removed





from the descriptor of the latter to allow for the rare instances when planar imaging is still used. In the view of the Committee, planar imaging is only ever used in extremely obese patients (> 200 kg) who cannot be accommodated on the camera table, or when there has been an equipment failure following injection of the radiopharmaceutical dose.

- △ While there were only eight services of item 61310 in 2014–15 there were 43 services in 2015–16, from different providers. Infarct avid imaging uses radiolabelled markers that accumulate in areas of damaged myocardium [5]. While largely superseded, it is still clinically appropriate and may have a place in rural and remote areas where access to MRI is limited, or in patients in whom MRI is contraindicated. The Committee considered deletion of this item but decided against this, noting there could be potential harm to patients if this was removed from the MBS.
- △ Item 61313 can be superior to echocardiography in some patients and remains the preferred method for assessing ejection fraction in patients with cancer, with 10% utilisation by cardiologists and 90% utilisation by oncologists. Removing the imaging technology from the descriptor will make the Schedule easier to interpret without having any effect on the eligible patient population.
- △ Item 61314 still has relevance for right ventricular function assessment, assessing changes in ejection fraction and cardiac shunts. While largely replaced by echocardiography, it is a robust and accurate assessment, especially in people with congenital heart disease, and should remain on the MBS. Consolidating items 61316, 61317, and 61320 into this item and removing reference to imaging technology in the descriptor of item 61414 will simplify the Schedule and make it easier to interpret, without having any effect on the eligible patient population.

## 1.2 General nuclear medicine item 61369—Indium-labelled octreotide study

Octreotide is a synthetic analogue of somatostatin. This is a diagnostic radiopharmaceutical used primarily in the assessment of neuroendocrine tumours (NETs) [2,6].

**Table 5: Introduction table for item 61369—Indium-labelled octreotide study**

Item number	Descriptor	Schedule fee	Volume of services (2014–15)	5-year service change (CAGR)	Benefits (2014–15)
61369	INDIUM-LABELLED OCTREOTIDE STUDY - including single photon emission tomography when undertaken, where: (a) there is a suspected gastro-entero-pancreatic endocrine tumour, based on biochemical evidence, with negative or equivocal conventional imaging; or (b) a surgically amenable gastro-entero-pancreatic endocrine tumour has been identified based on conventional techniques, in order to exclude additional disease sites. (R)	\$2,015.75	146	–28.9%	\$283,473



### 1.2.1 Recommendation 2

- △ Amend the descriptor for item 61369 to replace this test with a PET item utilising the radiopharmaceutical gallium-68 (<sup>68</sup>Ga) Dotatate.
- △ To refer this item to Medical Services Advisory Committee (MSAC), proposing that the descriptor for 61369 be amended, by substituting <sup>68</sup>Ga Dotatate, or a generic term, such as 'somatostatin-receptor scintigraphy' for indium-111 octreotide.
- △ To seek further advice from the Therapeutic Goods Administration (TGA) on the regulatory status of <sup>68</sup>Ga Dotatate and Ge/Ga generators.
- △ Until such time as the MSAC approves the isotope substitution, to increase the MBS fee to approximately \$4,000 for this item, as the current fee is grossly inadequate to cover the cost of importing indium-111 octreotide, [6] where the cost of the radiopharmaceutical (OctreoScan) alone in Australia is \$3,300 per vial [7].

### 1.2.2 Rationale 2

- △ The Committee considers <sup>68</sup>Ga Dotatate to be the best test for neuroendocrine tumours (NETs). It is significantly more accurate than indium-111 octreotide and available at lower cost. The literature supporting <sup>68</sup>Ga Dotatate in neuroendocrine tumours is large and robust.
- △ The European Neuroendocrine Tumour Society (ENETS) Consensus Guidelines, [8] UK and Ireland Neuroendocrine Tumour Society (UKINETS) Guidelines [9] and the [Clinical Oncology Society of Australia \(COSA\) NETS guidelines](#) [6] each endorse the use of <sup>68</sup>Ga Dotatate PET/CT in patients with NETs.
- △ Regulatory issues present one of the main obstacles to more widespread adoption of <sup>68</sup>Ga Dotatate as a diagnostic agent in Australia. <sup>68</sup>Ga Dotatate (Netspot®, Advanced Accelerator Applications USA, Inc.) has recently been approved by the US Food and Drug Administration (FDA) for supply in kit form, with the kit to be reconstituted at the site of administration. <sup>68</sup>Ga Dotatate is also widely available in Europe as an extemporaneously compounded product, although the availability and reimbursement varies within different European jurisdictions.
- △ However, currently there is no Ge/Ga generator listed on the Australian Register of Therapeutic Goods (ARTG) and no application to market this product in Australia has been received, limiting production of <sup>68</sup>Ga Dotatate to extemporaneous compounding in public hospitals and other sites where this is permitted under the *Therapeutic Goods Regulations 1990*.
- △ While there is evidence for the utility of <sup>68</sup>Ga Dotatate PET/CT in NETs other than gastro-entero-pancreatic endocrine tumours, the Committee agreed that the broadening of descriptor for item 61369 to include other NETs should be considered as a separate MSAC application in the future.

#### Progress on recommendations

- △ MSAC has endorsed the substitution of <sup>68</sup>Ga Dotatate for indium-111 octreotide in item 61369 following receipt of advice from the TGA about the manufacture and availability of <sup>68</sup>Ga Dotatate in Australia.
- △ The TGA's advice to MSAC was that a <sup>68</sup>Ga generator could be granted an exemption from listing on the ARTG, including exemption from GMP, with the manufacture of



<sup>68</sup>Ga Dotatate treated in a similar way to the extemporaneous compounding provisions that relate to other medicines, with individual practices taking responsibility for all aspects the product, from clinical use to quality control.

- △ A new item for <sup>68</sup>Ga Dotatate PET for gastro-entero-pancreatic neuroendocrine tumours (item 61647) was introduced on 1 May 2018.

### 1.3 Positron emission tomography (PET) items

Positron emission tomography (PET) is a nuclear medicine technology that uses short-lived radioisotopes to enable the non-invasive imaging of metabolic functions within the body. PET's main application is in the staging of various cancers and the monitoring of cancer therapies; however, it can also be used for imaging neurological conditions such as Alzheimer's disease [3].

#### Rules relating to PET services

As a component of its review of PET services, the Committee considered the appropriateness of current rules around the provision of, and claiming of Medicare benefits for, PET services in Australia as outlined in Schedule 1, Part 2, Division 2.4 of the Health Insurance (Diagnostic Imaging Services Table) Regulations 2017 (the DIST).

The Committee was asked to consider four aspects of PET service provision:

1. Current rules around who can supervise PET;
2. Current rules around who can claim Medicare benefits for PET;
3. The current definition of a "comprehensive facility" outlined in the DIST; and
4. The current requirement that each physician wishing to claim Medicare rebates for PET services must complete the Medicare Australia PET Statutory Declaration prior to performing Medicare-eligible services.

The Committee agreed current PET supervision rules remain appropriate. It acknowledged the current "grandfathering" provision (Division 2.4.3 of the DIST) which will gradually become redundant. It was agreed the rule stating all doctors reporting PET scans must be specifically trained for this purpose remains appropriate. The Committee discussed the fact that Australia currently has high standards of requirements for PET and agreed this should continue to be the case.

The Committee considered the appropriateness of current rules around who can claim Medicare benefits for PET. The Committee agreed the current high level of training requirements for claiming of benefits for PET services should remain. However, the Committee recommended the wording included in the accreditation standards be updated to reflect current standards specified by Australasian Association of Nuclear Medicine Specialists (AANMS).



The Committee considered the current definition of a “comprehensive facility” outlined in the DIST and whether this should be updated or removed.

- △ Section 2.4.2 of the DIST requires that Medicare-funded PET services are rendered in a 'comprehensive facility'. A comprehensive facility is defined in Clause 3 of the DIST (Part 3 – Dictionary) as follows:

*A building or part of a building, or more than one building, where all of the following services are performed: PET, computed tomography, diagnostic ultrasound, medical oncology, radiation oncology, surgical oncology and x-ray.*

The Committee agreed removal of the requirement may result in the proliferation of PET services without access to the multidisciplinary services complex cancer patients would require. The Committee discussed possible approaches to revising the definition. The Committee agreed on the imperative that the clinician reporting on the test possesses a thorough understanding of cancer care. However, it was acknowledged the definition may need to be refined to include a professional network of multidisciplinary health professionals rather than a physical facility as physical proximity to other services has become less relevant in modern practice. It was agreed patients need access to the full scope of multidisciplinary services. However, these would not necessarily be accessed on the same day and so may not need to be in close physical proximity to one another.

The Committee considered the following options:

- △ Remove the comprehensive facility definition entirely;
- △ Modify the current definition of a comprehensive facility for PET with the requirements to align with those for magnetic resonance imaging;
- △ Otherwise modify the definition of a comprehensive facility; or
- △ Retain existing requirements but review the situation again in three years.

The Committee acknowledged as there is currently good access to high-quality PET services in Australia, any changes to the standards should be undertaken with caution. The current requirements inhibit the proliferation of low-quality PET services without appropriate cancer service provision. The Committee agreed that PET should be performed in a hospital setting with the involvement of a radiation oncologist where appropriate.

At the conclusion of its deliberations, the Committee decided to retain the current definition of a “comprehensive facility” outlined in the DIST.

The Committee decided that all other existing PET rules should remain unchanged and agreed that this matter should be reviewed in three years.

## PET MBS items

There are currently 20 MBS PET items. Most MBS PET item descriptors date back to 2002 and, despite rapidly changing technology, the Schedule has not been updated since that time. Only a limited number of cancers are covered by the existing MBS PET item numbers, and each new PET item currently requires a lengthy and detailed submission to MSAC. This



means that many Australian patients, especially those with less common cancers, are currently disadvantaged by being unable to access MBS-rebated PET scans.

Therefore, the Committee recommends a modernisation of the Schedule with respect to PET items, to bring it in line with the changed clinical landscape.

### Co-claiming of CT with PET

The Committee discussed the current restriction preventing co-claiming of CT scan (item 61505) performed at the same time as PET and recommended that, as PET/CT has entirely replaced PET alone as standard of care in Australia, this restriction is obsolete and should be removed. Please see recommendation 22 (item 61505) for more details.

Remuneration for CT in addition to PET is included in the newly introduced item for <sup>68</sup>Ga Dotatate PET for gastro-entero-pancreatic neuroendocrine tumours (item 61647). To ensure consistency in remuneration between PET items, the Committee recommends reducing the schedule fee for item 61647 by the value of the fee for CT scan (item 61505). The reduced schedule fee is in response to the above recommendation and will not change the total remuneration for this procedure.

**Table 6: Introduction table for PET items**

Item	Descriptor	Scheduled fee	Service volume 2015–16*	5-year service change (CAGR)	Benefits (2015–16)*
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)	\$953.00	9032	15.6%	\$8,118,683
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)	\$953.00	5558	11.8%	\$4,994,042
61538	FDG PET study of the brain for evaluation of suspected residual or recurrent malignant brain tumour based on anatomical imaging findings, after definitive therapy (or during ongoing chemotherapy) in patients who are considered suitable for further active therapy. (R)	\$901.00	347	14.3%	\$292,724
61541	Whole body FDG PET study, following initial therapy, for the evaluation of suspected residual, metastatic or recurrent colorectal carcinoma in patients considered suitable for active therapy. (R)	\$953.00	8233	13.2%	\$7,406,620
61553	Whole body FDG PET study, following initial therapy, performed for the evaluation of suspected metastatic or	\$999.00	8796	25.0%	\$8,329,082



Item	Descriptor	Scheduled fee	Service volume 2015–16*	5-year service change (CAGR)	Benefits (2015–16)*
	recurrent malignant melanoma in patients considered suitable for active therapy. (R)				
61559	FDG PET study of the brain, performed for the evaluation of refractory epilepsy which is being evaluated for surgery. (R)	\$918.00	528	6.8%	\$456,870
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. (R)	\$953.00	2030	23.5%	\$1,825,100
61571	Whole body FDG PET study, for the further primary staging of patients with histologically proven carcinoma of the uterine cervix, at FIGO stage IB2 or greater by conventional staging, prior to planned radical radiation therapy or combined modality therapy with curative intent. (R)	\$953.00	650	32.9%	\$585,446
61575	Whole body FDG PET study, performed for the further staging of patients with confirmed local recurrence of carcinoma of the uterine cervix considered suitable for salvage pelvic chemoradiotherapy or pelvic exenteration with curative intent. (R)	\$953.00	527	0	\$475,201
61577	Whole body FDG PET study, performed for the staging of proven oesophageal or GEJ carcinoma. (R)	\$953.00	2452	11.7%	\$2,200,769
61598	Whole body FDG PET study performed for the staging of biopsy-proven newly diagnosed or recurrent head and neck cancer. (R)	\$953.00	4063	12.7%	\$3,661,485
61604	Whole body FDG PET study performed for the evaluation of patients with suspected residual head and neck cancer after definitive treatment, and who are suitable for active therapy. (R)	\$953.00	3898	17.6%	\$3,518,974
61610	Whole body FDG PET study performed for the evaluation of metastatic squamous cell carcinoma of unknown primary site involving cervical nodes. (R)	\$953.00	710	11.7%	\$636,185
61616	Whole body FDG PET study for the initial staging of indolent non-Hodgkin's lymphoma where clinical, pathological and imaging findings indicate that the stage is I or IIA and the proposed management is definitive radiotherapy with curative intent. (R)	\$953.00	847	–16.0%	\$756,725
61620	Whole body FDG PET study for the initial staging of newly diagnosed or previously untreated Hodgkin's or non-Hodgkin's lymphoma (excluding indolent non-Hodgkin's lymphoma. (R)	\$953.00	4091	0	\$3,645,362



Item	Descriptor	Scheduled fee	Service volume 2015–16*	5-year service change (CAGR)	Benefits (2015–16)*
61622	Whole body FDG PET study to assess response to first line therapy either during treatment or within three months of completing definitive first line treatment for Hodgkin's or non-Hodgkin's lymphoma (excluding indolent non-Hodgkin's lymphoma). (R)	\$953.00	5376	24.8%	\$4,847,029
61628	Whole body FDG PET study for restaging following confirmation of recurrence of Hodgkin's or non-Hodgkin's lymphoma (excluding indolent non-Hodgkin's lymphoma). (R)	\$953.00	3898	–0.3%	\$3,485,842
61632	Whole body FDG PET study to assess response to second-line chemotherapy when stem cell transplantation is being considered, for Hodgkin's or non-Hodgkin's lymphoma (excluding indolent non-Hodgkin's lymphoma). (R)	\$953.00	1040	0	\$ 937,130
61640	Whole body FDG PET study for initial staging of patients with biopsy-proven bone or soft tissue sarcoma (excluding gastrointestinal stromal tumour) considered by conventional staging to be potentially curable. (R)	\$999.00	1199	23.5%	\$1,130,929
61646	Whole body FDG PET study for the evaluation of patients with suspected residual or recurrent sarcoma (excluding gastrointestinal stromal tumour) after the initial course of definitive therapy to determine suitability for subsequent therapy with curative intent. (R)	\$999.00	2121	18.4%	\$2,009,726

\*Review of 2015–16 data not 2014–15 as for earlier items

### 1.3.1 Recommendation 3

- △ Expand the indications (cancer types) for Medicare-funded PET services to include all fluorodeoxyglucose (FDG)-avid solid tumours.
- △ To accompanying this change, consolidate all existing MBS PET items into four items, covering (a) diagnosis, (b) staging, (c) response assessment and (d) recurrence (re-staging) for all FDG-avid tumours.

### 1.3.2 Rationale 3

- △ The MBS PET items require a significant overhaul, consistent with UK and US guidelines:
  - The UK guidelines *Evidence-based recommendations for the use of PET-CT in the United Kingdom, 2016* [10] include a much wider range of FDG-avid tumours than is currently listed on the Australian MBS. The UK guidelines also endorse the use of non-FDG PET tracers for several tumour types and indications.
  - The US guidelines, CMBS Decision Memo for Positron Emission Tomography (FDG) for Breast Cancer [11] and CMBS Decision Memo for Positron Emission Tomography (FDG) for Solid Tumors [12] also follow a more inclusive approach, whereby access to PET scans is not limited by tumour type but is available to all patients with FDG-avid cancers.





- △ Both the Commonwealth Government's own data collection following initial approval of limited PET services in Australia, and the large National Oncologic PET Registry (NOPR) conducted by the CMBS in the United States, have demonstrated a significant impact of FDG PET on the management of nearly all solid tumours, in the order of 30-50% [13-16]. As a result, cancer care would likely be altered in large numbers of Australian patients if there was greater access to PET services before and during their treatment.
- △ Patients suffering from rare or uncommon cancers (which collectively make up approximately one-third of cancer diagnoses) are unlikely to ever receive approval for PET under the current, disease-specific MSAC processes. There are simply insufficient numbers of these patients to justify a multitude of separate MSAC applications for PET funding.
- △ In the process of this review, the Committee considered a written submission from the Oncology Clinical Committee (OCC) outlining their draft recommendations with respect to PET/CT. The OCC's recommendations with respect to FDG PET/CT items are closely aligned with those of the Committee; that is, a significant expansion of the indications for PET and a streamlining of PET item descriptors to remove their reference to a particular tumour type. Both Committees instead recommend four 'clinically-based indications' covering all FDG-avid tumours:
  - Diagnosis.
  - Staging.
  - Response assessment.
  - Suspected residual or recurrent cancer.
- △ The Committee acknowledges that the MBS Review is a finite process and implementation of many of its recommendations will necessarily involve processes outside its lifespan. Therefore, it recommends that DICC and OCC work together in establishing a cross-professional committee to develop an MSAC submission in support of the overhaul.
- △ The Committee also notes that PET now has many clinical indications other than cancer (e.g. infection), and that these new indications will need to be considered in the future by MSAC.

### 1.3.3 Recommendation 4

- △ Include in the *Explanatory Notes* of the MBS, a specific statement outlining those situations where co-claiming of diagnostic CECT with PET scans is considered inappropriate.
- △ The Provider Benefits Integrity Division of the Department of Health scrutinise the co-claiming of diagnostic CECT with PET scans.

### 4.3.4 Rationale 4

- △ The Committee received a written submission regarding potentially inappropriate co-claiming of diagnostic CECT with PET scans.
- △ The Committee noted that PET/CT is now routinely performed in Australia for anatomical localisation and attenuation correction, and agreed that combined PET/CT has proven advantages over stand-alone PET in terms of diagnostic





accuracy and diagnostic certainty. Combined PET/CT can obviate the need for separate CECT procedures in some cancer types (e.g. lymphoma).

- △ The Committee noted that diagnostic-quality, CECT has small, additional risks compared to the low-dose, non-contrast CT used routinely at the time of PET. These include increased patient radiation dose and the risks from the contrast administration.
- △ The Committee agreed that there are certain situations where administration of IV contrast for the CT component may improve the diagnostic accuracy of PET/CT, compared to non-contrast PET/CT, such as in patients with pelvic or neck tumours. Moreover, it is reasonable to perform CECT at the time of PET examination when both of these procedures will be required, as this can save patients time and inconvenience, and can potentially reduce the total patient radiation dose if this obviates the need for a separate, low-dose, non-contrast CT.
- △ The Committee was unanimously of the view that it is *inappropriate* to perform CECT together with a PET scan when:

- this has not been specifically requested by the referrer.

The Committee agreed that it is *inappropriate* for practice request forms to include a statement that diagnostic CECT is the default examination which will be performed with all PET studies.

- the patient has already had a diagnostic CECT examination recently performed.

This results in increased risk to the patient, and cost to government, for no additional value. In the experience of Committee members, most patients referred for PET have already received diagnostic CT examination prior to the referral. Indeed, it is frequently the diagnostic CT scan which prompts the PET referral.

- △ However, the Committee did not feel that it would be useful to amend PET item descriptors in light of the above, since there are times when a co-claimed CECT procedure is appropriate, and times when it is not.

### 1.3.4 Recommendation 5

- △ MSAC consider the inclusion on the MBS of <sup>68</sup>Ga-PSMA PET/CT for patients with prostate cancer.

### 1.3.5 Rationale 5

- △ Prostate-specific membrane antigen (PSMA) is over-expressed in the majority of patients with prostate cancer. This agent can be labelled with <sup>68</sup>Ga, and used to detect sites of prostate cancer which are invisible to other conventional imaging techniques. <sup>68</sup>Ga-PSMA has been demonstrated to have improved diagnostic accuracy compared to conventional imaging for the staging and re-staging of men with prostate cancer, principally through the detection of otherwise unsuspected sites of disease [18,19].
- △ In Australia, <sup>68</sup>Ga-PSMA PET/CT has already been shown to have substantial impact on management intent among men with newly diagnosed and recurrent prostate cancer; in a recently published, prospective, multicentre study, <sup>68</sup>Ga-PSMA PET/CT changed management intent in 21% of men with newly diagnosed prostate cancer



(primary staging) and in 62% of men with biochemical relapse following previous definitive therapy (re-staging).[20] In this study  $^{68}\text{Ga}$ -PSMA PET/CT revealed sites of unsuspected disease in the prostate bed (27% of patients), locoregional lymph nodes (39%) and at sites of distant metastasis (16%).

- △ Australia has been an early adopter of  $^{68}\text{Ga}$ -PSMA PET/CT and the modality is now offered in private practice settings in all states of the Commonwealth but is not yet funded universally, which has resulted in an equity gap, particularly if future research reaffirms the earlier results.
- △ Without pre-empting the results of current prospective research on the actual management of prostate cancer in Australian men, the Committee is of the view that  $^{68}\text{Ga}$ -PSMA PET/CT will need to be considered by MSAC for inclusion on the MBS in the near future. Because the radiopharmaceutical is extemporaneously compounded (like  $^{68}\text{Ga}$ -Dotatate) it is unlikely that there will be a commercial sponsor for an MSAC application and the Committee feels that it would be appropriate for MSAC to begin discussions with relevant stakeholders now, on the optimal approval pathway and evidence required.
- △ The Committee noted the rapid pace of research in relation to:
  - Fluorine-18-based PSMA ( $^{18}\text{F}$ -PSMA) imaging agents.
  - Phase II trials of Lutetium-177 ( $^{177}\text{Lu}$ -PSMA), both in Europe and in Australia, which have demonstrated a significant early response benefit in men with advanced, chemorefractory, castration-resistant prostate cancer. Phase III trials of this agent are now underway.
- △ The Committee agreed that these issues should be included in the horizon discussions with MSAC in relation to prostate cancer.



## 1.4 Group T3—Therapeutic nuclear medicine items

While nuclear medicine is primarily used for imaging purposes, it can also be used to treat some diseases and conditions. The dose of the radiopharmaceutical used in therapeutic nuclear medicine is usually higher, and may be administered directly to the organ being treated [3].

An MBS *Review of Funding for Diagnostic Imaging Services* in 2012 noted that ‘schedule fees for nuclear medicine services do not necessarily recognise the large variation in the cost of radiopharmaceuticals needed to perform them’, acknowledging that, in some instances, radiopharmaceutical costs can be higher than the schedule fee [21].

All therapeutic items on MBS remain clinically relevant but the availability and utilisation of these treatments in Australia is significantly affected by these pricing issues, with rebates failing to cover the cost of the radiopharmaceuticals.

**Table 7: Introduction table for therapeutic nuclear medicine items**

Item number	Descriptor	Schedule fee	Volume of services (2014–15)	5-year service change (CAGR)	Benefits (2014–15)
16003	INTRACAVITY ADMINISTRATION OF A THERAPEUTIC DOSE OF YTTRIUM 90 not including preliminary paracentesis, not being a service associated with selective internal radiation therapy or to which item 35404, 35406 or 35408 applies	\$650.50	63	–11.34%	\$32,741.75
16006	ADMINISTRATION OF A THERAPEUTIC DOSE OF IODINE 131 for thyroid cancer by single dose technique	\$499.85	703	6.88%	\$278,249.10
16009	ADMINISTRATION OF A THERAPEUTIC DOSE OF IODINE 131 for thyrotoxicosis by single dose technique	\$341.15	3320	1.80%	\$966,995.10
16012	INTRAVENOUS ADMINISTRATION OF A THERAPEUTIC DOSE OF PHOSPHOROUS 32	\$295.15	4	–7.79%	\$1,003.60
16015	ADMINISTRATION OF STRONTIUM 89 for painful bony metastases from carcinoma of the prostate where hormone therapy has failed and either: (i) the disease is poorly controlled by conventional radiotherapy; or	\$4,085.70	31	–20.40%	\$119,611.70



Item number	Descriptor	Schedule fee	Volume of services (2014–15)	5-year service change (CAGR)	Benefits (2014–15)
	(ii) conventional radiotherapy is inappropriate, due to the wide distribution of sites of bone pain				
16018	ADMINISTRATION OF <sup>153</sup> SM-LEXIDRONAM for the relief of bone pain due to skeletal metastases (as indicated by a positive bone scan) where hormonal therapy and/or chemotherapy have failed and either the disease is poorly controlled by conventional radiotherapy or conventional radiotherapy is inappropriate, due to the wide distribution of sites of bone pain.	\$2,442.45	14	–15.76%	\$32,571.10

#### 1.4.1 Recommendation 6

- △ The Department of Health to liaise with the Pharmaceutical Benefits Scheme regarding transfer of funding for therapeutic radionuclides from the MBS to the PBS.
- △ As an interim measure, the fees for these items be increased so that they adequately cover the cost of the radiopharmaceuticals and their administration.
- △ The Department of Health to continue to vigorously pursue listing of Radium-223.

#### 1.4.2 Rationale 6

- △ All therapeutic items on MBS remain clinically relevant, but availability and use are affected by price; this explains the low service volumes for some items. Furthermore, a significant number of therapeutic nuclear medicine procedures performed in public hospitals will not be captured by Medicare and so the true utilisation in Australia is likely higher than is indicated by MBS data.
- △ The Committee feels that radiopharmaceuticals could be considered for listing on the PBS, as the PBS schedule is more flexible with respect to pricing; however, currently there is no mechanism to fund radiopharmaceuticals under the PBS. Radiopharmaceuticals are classified by the TGA as ‘medicines’ but are the only therapeutic drugs funded through the MBS, rather than the PBS.
- △ Radiopharmaceutical pricing around Australia is not fixed, with the price varying according to individually negotiated contracts between suppliers and practices. It is not possible to quote a ‘catalogue price’ in relation to radiopharmaceuticals, however, an illustrative example of current prices quoted to a large Australian hospital is provided in Table 9 to indicate the magnitude of the problem.

**Table 8: Radiopharmaceutical prices (illustrative example) and MBS fees**

Radiopharmaceutical	Item No.	MBS Fee (AUD) <sup>1</sup>	Quoted Price (AUD) <sup>2</sup>	Notes
Y-90 citrate (for intracavity administration)	16003	650.50	2,169.00	1,100 MBq Can be used for up to 4 patients, depending on indication and demand
I-131 (thyroid cancer)	16006	499.85	652.86	3.7 GBq
I-131 (thyrotoxicosis)	16009	341.15	313.50	600 MBq
P-32	16012	295.15	2,250.00	185 MBq
Sr-89	16015	4,085.70	3,750.00	150 MBq
Sm-153 lexidronam	16018	2,442.45	4,130.06	6.0 GBq Typical dose required for 80 kg patient = 3.0–4.5 GBq

1. Fee includes radiopharmaceutical and administration
2. Excluding delivery fee. Correct at 26/09/2017, for delivery to a large Australian metropolitan hospital.

- △ Items 16015 (Strontium-89) and 16018 (Samarium-153) need to remain on the Schedule for prostate cancer, at least until radium-223 is listed on the MBS. Radium-223 is a superior alternative to strontium-89 and samarium-153 lexidronam in prostate cancer because it has been shown to prolong life as well as alleviate pain from skeletal metastasis [22].
- △ MSAC has approved radium-223 for MBS listing; however, the sponsor has not proceeded with listing due to commercial reasons with respect to price disclosure. The Department has, to date, been unable to progress the listing of radium-223 on the MBS. The Committee expressed its disappointment that a MSAC-endorsed therapeutic item had not found its way onto the schedule due to a breakdown in negotiations between Government and the sponsor, and questioned whether the commercial strategy used as the basis for negotiations to date was appropriate, given that it had not resulted in a successful outcome.

#### ***Progress on recommendations***

- △ The PBAC has committed to reviewing radium-223 for possible listing on the PBS. This may impact all other radioisotopes that are used for therapeutic purposes.



### 1.4.3 Recommendation 7

- △ The Department of Health consult with the TGA, the Australian Nuclear Science and Technology Organisation (ANSTO) and MSAC to establish preliminary processes for the registration and approval of Lu-177 octreotate and other therapeutic nuclear medicine items which are on the clinical horizon.

### 1.4.4 Rationale 7

- △ The Committee raised, as a horizon issue, Lu-177 octreotate therapy for inoperable progressive NETs, noting that use of this agent should logically be considered alongside use of <sup>68</sup>Ga Dotatate (Section 4.2) , as the pair function as a ‘theranostic dyad’.
- △ Radiopeptide therapy is supported by UKINETS [9] and ENETS [8] guidelines and the NETTER-1 phase III trial, [23] which demonstrated superiority over somatostatin analogues currently funded under the PBS, and at lower cost. There are trials ongoing in Australia of Lu-177 octreotate in combination with chemotherapy. This is likely to be the first of a number of theranostic dyads that will imminently require consideration for funding, with Lu-PSMA (prostate-specific membrane antigen therapy) for prostate cancer likely to follow soon after.
- △ Advanced Accelerator Applications USA, Inc. (AAA). has filed an application with the FDA for approval of Lutathera® (Lu-177 octreotate) in the US, and with the Medicines and Healthcare Products Regulatory Agency (MHRA) in the UK, but the patent applies only in the northern hemisphere, so Australian sites are currently eligible to use compounded versions of this product without infringing patent law.
- △ As the price for reimbursement sought by AAA in the northern hemisphere is many times higher than the price of extemporaneously prepared product in Australia, early approval of this agent could potentially achieve large financial savings for the Australian government.

## 1.5 Interventional radiology procedures—Item 35404

SIR-spheres are yttrium-90 resin microspheres that are implanted into malignant liver tumours to selectively deliver high doses of ionising radiation to the tumour.

**Table 9: Introduction table for item 35404—Dosimetry, handling and injection of SIR-spheres**

Item number	Descriptor	Schedule fee	Volume of services (2015–16)*	5 year service change (CAGR)*	Benefits (2015–16)*
35404	DOSIMETRY, HANDLING AND INJECTION OF SIR-SPHERES for selective internal radiation therapy of hepatic metastases which are secondary to colorectal cancer and are not suitable for resection or ablation, used in combination with systemic chemotherapy	\$346.60	195	1.8%	\$48,162



Item number	Descriptor	Schedule fee	Volume of services (2015–16)*	5 year service change (CAGR)*	Benefits (2015–16)*
	<p>using 5-fluorouracil (5FU) and leucovorin, not being a service to which item 35317, 35319, 35320 or 35321 applies</p> <p>The procedure must be performed by a specialist or consultant physician recognised in the specialties of nuclear medicine or radiation oncology on an admitted patient in a hospital. To be claimed once in the patient's lifetime only.</p>				

\*Review of 2015–16 data not 2014–15 as for earlier items

### 1.5.1 Recommendation 8

- △ To expand the patient population for this item to include other cancer types and in combination with other chemotherapy regimens for which there is clinical evidence of effectiveness.
- △ Amend the item descriptor to remove '*once in a patient's lifetime only*'.

### 1.5.2 Rationale 8

- △ Selective internal radiation therapy (SIRT) is FDA approved and has clinical evidence for effectiveness for metastatic colorectal cancer, [24] neuroendocrine tumours, [25,26] other liver-dominant metastatic tumours (e.g. breast cancer), [27,28] cholangiocarcinoma [29] and hepatocellular carcinoma [30].
- △ At the time of the Committee's review, a contracted assessment of SIR-sphere items (35404, 35406 and 35408) was being undertaken for an MSAC review, following publication of the results of the [SIRFLOX study](#) [24].
- △ However, as the current MSAC assessment was restricted to colorectal cancer, the Committee recommended this be expanded to consider the wider range of cancers where SIRT had clinical evidence of effectiveness.
- △ The Department subsequently consulted with the sponsor SIRTEx, which has agreed to an expanded MSAC assessment of SIRT covering the following indications:
  - metastatic colorectal cancer
  - liver dominant tumours (including breast cancer)
  - neuroendocrine tumours (NETs)
  - hepatocellular carcinoma (HCC)
  - cholangiocarcinoma.

The sponsor's application was considered by the PICO Advisory Sub-committee (PASC) at their April 2017 meeting but is currently listed on the MSAC website as ON HOLD.



- △ The 'once in a patient's lifetime' restriction in the descriptor is no longer appropriate, as there is evidence that this treatment can be administered more than once.

## 1.6 Group D2 — Nuclear medicine non-imaging items

Many of the items in this part of the Schedule are now considered obsolete and have been recommended for deletion.

**Table 10: Introduction table for non-imaging items 12503, 12506, 12509, 12512, 12515, 12518, 12521, 12530**

Item number	Descriptor	Schedule fee	Volume of services (2014–15)	5-year service change (CAGR)	Benefits (2014–15)
12503	ERYTHROCYTE RADIOACTIVE UPTAKE SURVIVAL TIME TEST OR IRON KINETIC TEST	\$424.75	3	24.7%	\$1,040
12506	GASTROINTESTINAL BLOOD LOSS ESTIMATION involving examination of stool specimens	\$303.30	2	14.87%	\$297
12509	GASTROINTESTINAL PROTEIN LOSS	\$216.65	0	0	\$0.00
12512	RADIOACTIVE B12 ABSORPTION TEST 1 isotope	\$105.05	1	–19.73%	\$89
12515	RADIOACTIVE B12 ABSORPTION TEST 2 isotopes	\$229.85	0	0	\$0.00
12518	THYROID UPTAKE (using probe)	\$105.05	2	7.79%	\$178
12521	PERCHLORATE DISCHARGE STUDY	\$125.21	0	0	\$0.00
12530	WHOLE BODY COUNT not being a service associated with a service to which another item applies	\$126.25	74	–3.19%	\$7,969

### 1.6.1 Recommendation 9

- △ Delete items 12503, 12506, 12509, 12512, 12515, 12518, 12521 and 12530 from the Schedule as they are now obsolete.

### 1.6.2 Rationale 9

- △ These non-imaging items are obsolete and largely superseded by other tests, reflected in the very low or zero service volumes.

## 1.7 General nuclear medicine lung items – 61328, 61340, 61348

Indications for these items include pre-operative assessment for lung volume reduction surgery, assessment of activity of inflammatory lung disease and suspected pulmonary embolism [2].

**Table 11: Introduction table for items 61328, 61340, 61348—Lung items**

Item number	Descriptor	Schedule fee	Volume of services (2014–15)	5-year service change (CAGR)	Benefits (2014–15)
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61328	LUNG PERFUSION STUDY, with planar imaging and single photon emission tomography OR planar imaging, or single photon emission tomography. (R)	\$227.65	465	10.1%	\$94,688
61340	LUNG VENTILATION STUDY using aerosol, technegas or xenon gas, with planar imaging and single photon emission tomography OR planar imaging or single photon emission tomography. (R)	\$253.00	135	-5.4%	\$31,141
61348	LUNG PERFUSION STUDY AND LUNG VENTILATION STUDY using aerosol, technegas or xenon gas, with planar imaging and single photon emission tomography, OR planar imaging, or single photon emission tomography. (R)	\$443.35	20,841	5.2%	\$8,321,791

### 1.7.1 Recommendation 10

- △ Amend the item descriptors for items 61328, 61340 and 61348 to remove reference to the imaging technique (Table 17).
- △ Amend the MBS explanatory notes for items 61328, 61340 and 61348 as per the PE/DVT Working Group draft recommendations:
  - Medical practitioners referring patients for imaging for suspected PE (items 57351, 57356, 61328, 61340, 61348) should read and consider the RANZCR 2015 Choosing Wisely recommendations available at [www.choosingwisely.org.au/recommendations/ranzcr](http://www.choosingwisely.org.au/recommendations/ranzcr), or such clinical RANZCR Choosing Wisely recommendations as succeed it.

**Table 12: Proposed changes to items 61328, 61340 and 61348**

Item	Current descriptor	Revised descriptor
61328	LUNG PERFUSION STUDY, with planar imaging and single photon emission tomography OR planar imaging, or single photon emission tomography. (R)	LUNG PERFUSION STUDY (R)
61340	LUNG VENTILATION STUDY using aerosol, technegas or xenon gas, with planar imaging and single photon emission tomography OR planar imaging or single photon emission tomography. (R)	LUNG VENTILATION STUDY (R)
61348	LUNG PERFUSION STUDY AND LUNG VENTILATION STUDY using aerosol, technegas or xenon gas, with planar imaging and single photon emission tomography, OR planar imaging, or single photon emission tomography. (R)	LUNG PERFUSION STUDY AND LUNG VENTILATION STUDY (R)

### 1.7.2 Rationale 10

- △ The suggested change to the descriptors will make them easier to interpret, without having any effect on the eligible patient population.
- △ The Choosing Wisely recommendation from Royal Australian and New Zealand College of Radiologists (RANZCR) recommends the use of clinical decision rules to prevent unnecessary imaging for pulmonary embolism (PE) in low-risk groups:



- Don't request any diagnostic testing for suspected pulmonary embolism (PE) unless indicated by Wells Score (or Charlotte Rule) followed by PE Rule-out Criteria (in patients not pregnant). Low risk patients in whom diagnostic testing is indicated should have PE excluded by a negative D dimer, not imaging [31].
- △ PE can be excluded in low-risk patients by a negative result on whole blood D dimer. Some low-risk patients ('Pulmonary Embolism Rule-out Criteria [PERC] negative') are at such low risk they require no diagnostic testing, including D dimer [31].

## 1.8 General nuclear medicine liver and spleen items—61352, 61353, 61356

Liver and spleen studies may assist in the diagnosis of focal disease (e.g. tumour, abscess, trauma), chronic liver disease, portal hypertension and haemangioma [2].

**Table 13: Introduction table for items 61352, 61353, 61356—Liver and spleen items**

Item number	Descriptor	Schedule fee	Volume of services (2014–15)	5-year service change (CAGR)	Benefits (2014–15)
61352	LIVER AND SPLEEN STUDY (colloid) - planar imaging. (R)	\$259.35	69	1.2%	\$13,884
61353	LIVER AND SPLEEN STUDY (colloid), with single photon emission tomography and with planar imaging when undertaken. (R)	\$386.60	209	–7.9%	\$74,444
61356	RED BLOOD CELL SPLEEN OR LIVER STUDY, including single photon emission tomography when undertaken. (R)	\$392.80	299	–11.5%	\$109,363

### 1.8.1 Recommendation 11

- △ Delete item 61352.
- △ Amend descriptors for items 61353 and 61356 to remove reference to the imaging technology (see Table 14, below).

**Table 14: Proposed changes to items 61352, 61353 and 61356**

Item	Current descriptor	Proposed change/ Revised descriptor
61352	LIVER AND SPLEEN STUDY (colloid) - planar imaging. (R)	Delete
61353	LIVER AND SPLEEN STUDY (colloid), with single photon emission tomography and with planar imaging when undertaken. (R)	LIVER AND SPLEEN STUDY (colloid) (R)
61356	RED BLOOD CELL SPLEEN OR LIVER STUDY, including single photon emission tomography when undertaken. (R)	RED BLOOD CELL SPLEEN OR LIVER STUDY (R)



### 1.8.2 Rationale 11

- △ Planar imaging is largely superseded technology (item 61352), replaced by single photon emission computed tomography (SPECT) in almost all cases.

## 1.9 General nuclear medicine hepatobiliary items—61360 and 61361

Nuclear medicine hepatobiliary studies are indicated for assessment of biliary tract function in conditions such as cholecystitis and biliary obstruction [2].

**Table 15: Introduction table for items 61360 and 61361—Hepatobiliary studies**

Item number	Descriptor	Schedule fee	Volume of services (2014–15)	5-year service change (CAGR)	Benefits (2014–15)
61360	HEPATOBILIARY STUDY, including morphine administration or pre-treatment with a cholagogue when performed. (R)	\$403.35	2059	0.4%	\$761,910
61361	HEPATOBILIARY STUDY with formal quantification following baseline imaging, using a cholagogue. (R)	\$461.40	3802	1.1%	\$1,623,167

### 1.9.1 Recommendation 12

- △ Amend the explanatory notes for items 61360 and 61361 to remove reference to a specific product (CCK/sincalide), to align the explanatory notes with the wording of the item descriptors.

### 1.9.2 Rationale 12

- △ Sincalide is no longer listed on the ARTG, and the explanatory note for these items should refer to 'any cholagogue', without specifying a particular agent.

## 1.10 Testicular study—item 61401

**Table 16: Introduction table for item 61401—Testicular study**

Item number	Descriptor	Schedule fee	Volume of services (2014–15)	5-year service change (CAGR)	Benefits (2014–15)
61401	TESTICULAR STUDY. (R)	\$162.30	0	0	0

### 1.10.1 Recommendation 13

- △ Delete item 61401, as this test is now obsolete.

### 1.10.2 Rationale 13

- △ This item is obsolete and has been replaced by scrotal ultrasound (MBS item 55023). There were zero services for item 61401 in 2014–15.



### 1.11 Brain study with blood brain barrier agent—item 61405

Table 17: Introduction table for item 61405—Brain study with blood brain barrier agent

Item number	Descriptor	Schedule fee	Volume of services (2014–15)	5-year service change (CAGR)	Benefits (2014–15)
61405	BRAIN STUDY WITH BLOOD BRAIN BARRIER AGENT, with planar imaging and single photon emission tomography, OR planar imaging, or single photon emission tomography. (R)	\$346.00	19	–12.9%	\$5,655

#### 1.11.1 Recommendation 14

- △ Delete item 61405, as the test is now obsolete.

#### 1.11.2 Rationale 14

- △ This item is obsolete and has been replaced as an imaging test by computed tomography (CT).

### 1.12 Cerebro-spinal fluid transport study—item 61409

Despite the low volume of services, this test remains clinically relevant. Its principal indication is hydrocephalus. The test always follows neurologist referral.

Table 18: Introduction table for item 61409 – Cerebro-spinal fluid transport study

Item number	Descriptor	Schedule fee	Volume of services (2014–15)	5-year service change (CAGR)	Benefits (2014–15)
61409	CEREBRO-SPINAL FLUID TRANSPORT STUDY, with imaging on 2 or more separate occasions. (R)	\$873.50	91	5.7%	\$66,117

#### 1.12.1 Recommendation 15

- △ To increase the MBS fee for item 61409 so that the fee adequately covers the cost of the radiopharmaceutical used in the scan.

#### 1.12.2 Rationale 15

- △ The current fee is inadequate to the cover cost of the radioisotope. The approved agent for this purpose is In-111 DTPA, which can only be sourced from the US. The fee quoted to the same large Australian hospital for this agent is \$3,485.00 (correct as at 27/09/17).



### 1.13 Dynamic blood flow/regional blood volume quantity study—item 61417

**Table 19: Introduction table for item 61417—Dynamic blood flow/regional blood volume quantity study**

Item number	Descriptor	Schedule fee	Volume of services (2014–15)	5-year service change (CAGR)	Benefits (2014–15)
61417	DYNAMIC BLOOD FLOW STUDY OR REGIONAL BLOOD VOLUME QUANTITATIVE STUDY, not being a service associated with a service to which another item in this Group applies. (R)	\$118.85	6	–3.0%	\$620

#### 1.13.1 Recommendation 16

△ Delete item 61417, as this test is now obsolete.

#### 1.13.2 Rationale 16

△ The item is considered obsolete and has been replaced by other forms of imaging (e.g. angiography, ultrasound). The Committee noted very low service volumes in 2014–15.

### 1.14 General nuclear medicine thallium studies—items 61437, 61438, 61458 and 61461

Thallium studies are used to diagnose and monitor malignancy [2].

**Table 20: Introduction table for items 61437, 61438, 61458 and 61461—Thallium studies**

Item number	Descriptor	Schedule fee	Volume of services (2014–15)	5-year service change (CAGR)	Benefits (2014–15)
61437	WHOLE BODY STUDY using thallium. (R)	\$542.75	144	–6.6%	\$72,656
61438	WHOLE BODY STUDY using thallium, with single photon emission tomography. (R)	\$672.95	725	11.4%	\$459,948
61458	LOCALISED STUDY using thallium. (R)	\$396.95	5	–35.3%	\$1,806
61461	LOCALISED STUDY using thallium, with single photon emission tomography. (R)	\$527.85	38	–4.6%	\$18,539

#### 1.14.1 Recommendation 17

△ Delete item 61437 as this test is now obsolete.



- △ Amend the descriptor of item 61438 to remove reference to the imaging technology (Table 21).
- △ Delete item 61458, as this test is now obsolete.
- △ Amend the descriptor of item 61461 to remove reference to the imaging technology (Table 21).

**Table 21: Proposed changes to Gallium, technetium and thallium studies**

Item	Current descriptor	Proposed change/ Revised descriptor
61437	WHOLE BODY STUDY using thallium. (R)	Delete
61438	WHOLE BODY STUDY using thallium, with single photon emission tomography. (R)	WHOLE BODY STUDY using thallium. (R)
61458	LOCALISED STUDY using thallium. (R)	Delete
61461	LOCALISED STUDY using thallium, with single photon emission tomography. (R)	LOCALISED STUDY using thallium. (R)

### 1.14.2 Rationale 17

- △ Planar imaging, used in item 61437, is superseded technology. However, amending the descriptor of 61438 allows item 61437 to be removed from the MBS without disadvantaging patients.
- △ Planar imaging, used in item 61458, is superseded technology. However, amending the descriptor of 61461 allows item 61458 to be removed from the MBS without disadvantaging patients.

## 1.15 Repeat planar and SPECT imaging, or repeat planar or SPECT imaging where the previous scan was abnormal or equivocal—item 61462

Item 61462 can only be co-claimed, and is indicated when an earlier nuclear medicine scan is abnormal or equivocal. The test involves no additional administration of radiopharmaceutical. Due to the long half-lives of many radiopharmaceuticals, it can be appropriate to co-claim this item up to 10 days after the original scan.

The Committee also considered a submission from the Department, where this item was being claimed frequently by a single practice in relation to lymphoscintigraphy (item 61469).

**Table 22: Introduction table for item 61462—Repeat planar and SPECT imaging, or repeat planar or SPECT imaging where the previous radionuclide scan was abnormal or equivocal**

Item number	Descriptor	Schedule fee	Volume of services (2014–15)	5-year service change (CAGR)	Benefits (2014–15)
61462	REPEAT PLANAR AND SINGLE PHOTON EMISSION TOMOGRAPHY IMAGING, OR REPEAT PLANAR IMAGING OR SINGLE PHOTON EMISSION TOMOGRAPHY IMAGING on an occasion subsequent to the performance of any one of items 61364, 61426, 61429, 61430, 61442, 61450, 61453, 61469, 61484 or 61485 where there	\$129.00	3,329	6.7%	\$370,131



Item number	Descriptor	Schedule fee	Volume of services (2014–15)	5-year service change (CAGR)	Benefits (2014–15)
	is no additional administration of radiopharmaceutical and where the previous radionuclide scan was abnormal or equivocal. (R)				

#### 1.15.1 Recommendation 18

- △ Amend the descriptor information for item 61462 by removing reference to co-claiming with item 61484.
- △ Discourage inappropriate co-claiming of this item by referring to the Provider Benefits Integrity Division of the Department of Health Services.

#### 1.15.2 Rationale 18

- △ Item 61484 has been recommended for deletion and so needs to be removed from the descriptor.
- △ The Committee considered the submission by the Department in relation to the frequent co-claiming of this item in relation to item 61469 (lymphoscintigraphy) and agreed that this practice is generally *inappropriate*, particularly if this is the first attempt at imaging the patient. Rather than amend the item descriptor, the Committee felt that the practice in question should be referred to the Provider Benefits Integrity Division of the Department of Health Services.

### 1.16 General nuclear medicine thyroid study—item 61473

This item is indicated for investigation of hyperthyroidism, thyroid enlargement (goitre) and thyroid nodules [2].

**Table 23: Introduction table for item 61473—Thyroid study**

Item number	Descriptor	Schedule fee	Volume of services (2014–15)	5-year service change (CAGR)	Benefits (2014–15)
61473	THYROID STUDY including uptake measurement when undertaken. (R)	\$175.40	25,992	2.09%	\$4,246,949

#### 1.16.1 Recommendation 19

- △ Amend the descriptor of item 61473 to *THYROID STUDY*.

#### 1.16.2 Rationale 19

- △ The Committee considers it is no longer necessary to include the words *including uptake measurement when undertaken*, since the benefit is payable in either instance. The removal of item 12518 should eliminate any potential for double-claiming in this situation.



### 1.17 Parathyroid study—item 61480

The item is indicated for assessment of parathyroid adenoma or hyperparathyroidism [2].

**Table 24: Introduction table for item 61480—Parathyroid study**

Item number	Descriptor	Schedule fee	Volume of services (2014–15)	5-year service change (CAGR)	Benefits (2014–15)
61480	PARATHYROID STUDY, planar imaging and single photon emission tomography when undertaken. (R)	\$396.85	6784	11.53%	\$2,453,965

#### 1.17.1 Recommendation 20

- △ To amend the descriptor for item 61480 to remove reference to imaging technology. Descriptor to read: *PARATHYROID STUDY*.

#### 1.17.2 Rationale 20

- △ The descriptor currently specifies *planar and SPECT imaging when undertaken*. This is unnecessary, given that all parathyroid scans are planar and/or SPECT.

### 1.18 Adrenal studies —items 61484, 61485

These items are indicated for investigation of suspected pheochromocytoma or other tumours of the adrenal medulla [2].

**Table 25: Introduction table for items 61484—Adrenal study**

Item number	Descriptor	Schedule fee	Volume of services (2014–15)	5-year service change (CAGR)	Benefits (2014–15)
61484	ADRENAL STUDY. (R)	\$880.85	72	–14.55%	\$59,354
61485	ADRENAL STUDY, with single photon emission tomography (R)	\$999.20	403	0.66%	\$373,859

#### 1.18.1 Recommendation 21

- △ Delete item 61484, as the test is now obsolete.
- △ Increase the fee of item 61485 to cover the cost of the radiopharmaceutical.





### 1.18.2 Rationale 21

- △ The item is obsolete, as all studies should now be performed using SPECT (MBS item 61485).
- △ At the same large Australian hospital used as a reference point for prices for other radiopharmaceuticals, the cost of a 200 MBq dose of <sup>123</sup>I-MIBG is \$1,523.92. The MBS fee for item 61485 is \$999.20.

## 1.19 CT scan performed with SPECT for anatomic localisation/attenuation correction—item 61505

**Table 26: Introduction table for item 61505—CT scan performed at the same time and covering the same body area as SPECT for anatomical localisation or attenuation correction**

Item number	Descriptor	Schedule fee	Volume of services (2014–15)	5-year service change (CAGR)	Benefits (2014–15)
61505	CT scan performed at the same time and covering the same body area as single photon emission tomography for the purpose of anatomic localisation or attenuation correction where no separate diagnostic CT report is issued and only in association with items 61302 – 61650. (R)	\$100.00	219,694	25.41%	\$19,456,394

### 1.19.1 Recommendation 22

- △ Amend the descriptor to specify that item 61505 can be co-claimed with items in the range of 61302 –61650, including both single photon emission tomography (SPET) and positron emission tomography (PET) items.

### 1.19.2 Rationale 22

- △ This item, for CT performed at same time as SPECT for anatomical localisation and attenuation correction, has undergone rapid growth in services in recent years. The Committee considered that there are multiple factors contributing to this growth, including improved diagnostic accuracy and certainty compared with SPECT alone, referrer expectations, specific guideline and protocol recommendations for CT attenuation correction from some learned societies, and the now-widespread availability of hybrid SPECT/CT systems throughout Australia.
- △ In 2015–16 item 61505 was claimed most often with item 61425 (Bone study) and the combination of items 11712/61307 (stress ECG and Combined stress and rest myocardial perfusion study). Both these practices are clinically appropriate. The American Society of Nuclear Cardiology, The Society of Nuclear Medicine & Molecular Imaging (SNMMI) [32] and the European Association of Nuclear Medicine [33] recommend CT attenuation correction for cardiac studies.
- △ The Committee considered whether 61505 could be removed from the MBS and instead absorbed into the items it was regularly co-claimed with (that is, incorporating a CT component with corresponding fee increase in these items). However, the Committee ultimately rejected this suggestion, believing it would remove the clinician's discretion to



order 61505 only when clinically required, including for some less regularly co-claimed items.

- △ The Committee noted that 61505 was occasionally co-claimed with PET items in 2015–16, a practice that is **currently** prohibited in the *Regulations* and in the **item descriptor**. However, the current item descriptor for 61505 is ambiguously worded, as the range of items it currently specifies (61302–61650) can be co-claimed with 61505 includes the PET item numbers. **In order to remove such ambiguity**, the Committee **recommends** that the **item** descriptor **would need to be** amended to make it clear that PET items can be co-claimed with item 61505.
- △ When the PET item numbers were first developed by MSAC, many of the nation's limited fleet of PET scanners at that time had been purchased by state and/or Commonwealth governments and PET/CT scanners did not exist, so no capital component was included in the fee. Since that time, PET in Australia has been entirely supplanted by PET/CT, which is now standard of care. Indeed, stand-alone PET scanners are no longer offered for purchase in Australia. Further, PET is now widely performed in private practice settings in this country.
- △ The recent inclusion on the MBS of item 61647 for Ga-68 peptide PET for staging of gastroenteropancreatic neuroendocrine tumours does include a component for co-registered CT in the fee, which is specifically detailed in the item descriptor.
- △ At the present time, therefore, a MBS payment exists for co-registered CT when performed together with a SPECT examination or Ga-68 peptide PET, but not for F-18 FDG PET. The Committee noted the logical inconsistency in this approach and unanimously supported the proposition that co-registered CT should be reimbursed across the range of nuclear medicine diagnostic procedures, including PET.
- △ If PET item numbers are eligible to be co-claimed with the co-registered CT item number (61505), then one of two approaches is required: (a) the restriction on co-claiming of item 61505 with PET items should be removed, and the fee for item 61647 should be reduced by the amount reimbursed by 61505 (in line with the multiple services rule) in order to avoid double payment, or (b) the restriction on co-claiming item 61505 with PET items be retained, and the fee for F-18 FDG PET items (61523-61646) be increased to match the fee for the newly introduced Ga-68 peptide PET/CT (61647).
- △ The Committee recommends allowing PET items to be co-claimed with item 61505 and reducing the fee for item 61647 by the value reimbursed for item 61505. The Committee did not have a strong view on which of the above two approaches was preferable but the first requires revision of two items (61505 and 61647), while the second requires revision of the wording of 19 PET item descriptors.

## 1.20 FET PET in Patients with Malignant Brain Tumours

### 1.20.1 Recommendation 23

- △ Create a new item for use of 18F-fluoro-ethyl-tyrosine (FET) with PET in patients with malignant brain tumours.



### 1.20.2 Rationale 23

- △ The Committee noted the current clinical use of FET PET scans for patients with malignant brain tumours, considered superior to the currently MBS funded FDG PET in nearly all cases. FET is a tumour imaging agent that measures cell proliferation, rather than rate of metabolism and shows it's greatest role in neuro-oncology. It can be used to refine radiotherapy target volumes and is useful to distinguish tumour recurrence from radio-necrosis in cases where MRI is equivocal.
- △ The Committee noted that use of FET requires registration and approval with the TGA before it can be progressed to MSAC. This agent needs to be listed on the Australian Register of Therapeutic Goods before MSAC will consider an application including its administration.

## 1.21 Dopaminergic Brain Imaging for the evaluation of patients with movement disorders

### 1.21.1 Recommendation 24

- △ Create a new item for use of <sup>18</sup>F-DOPA L-6-[<sup>18</sup>F] fluoro-3,4-dihydroxyphenylalanine (F-DOPA) PET for the evaluation of patients with movement disorders (Parkinsonism or similar) where the diagnosis remains uncertain after clinical assessment by a consultation physician and conventional imaging.

### 1.21.2 Rationale 24

- △ The Committee noted that in Europe and North America patients with Parkinsonian syndromes are eligible for funded brain imaging using I-123 FP-CIT (DATscan®), marketed by GE Healthcare. DATscan has been shown to change diagnosis and management in more than half of patients referred, however it is not marketed or available in Australia. F-DOPA and F-Dopamine PET can both be used to examine the striatal system, with F-DOPA showing equivalent diagnostic accuracy to DATscan (Ref).
- △ Parkinson's disease is the second most common neurological disorder after Alzheimer's disease and despite this imaging technique's effectiveness in diagnosis and assessment of disease progression in terms of the dopaminergic degeneration, it remains unavailable to the Australian population.
- △ The Committee noted that use of F-DOPA requires registration and approval with the TGA before it can be progressed to MSAC. This agent needs to be listed on the Australian Register of Therapeutic Goods before MSAC will consider an application including its administration.

## 1.22 Items with no changes

The Committee recommended that the MBS items listed in Table 32 do not require amendment. Despite low service volumes for some items, they remain clinically appropriate.



Table 27: MBS items that do not require amendment

Item	Item descriptor	Schedule fee	Services FY 2014–15
12500	BLOOD VOLUME ESTIMATION	\$216.65	122
12524	RENAL FUNCTION TEST (without imaging procedure)	\$158.35	777
12527	RENAL FUNCTION TEST (with imaging and at least 2 blood samples)	\$84.95	74
12533	CARBON-LABELLED UREA BREATH TEST using oral C-13 or C-14 urea, performed by a specialist or consultant physician, including the measurement of exhaled $^{13}\text{CO}_2$ or $^{14}\text{CO}_2$ , for either:- (a) the confirmation of <i>Helicobacter pylori</i> colonisation, OR (b) the monitoring of the success of eradication of <i>Helicobacter pylori</i> . not being a service to which 66900 applies	\$84.65	23,682
61364	BOWEL HAEMORRHAGE STUDY (R)	\$496.95	235
61368	MECKEL'S DIVERTICULUM STUDY (R)	\$223.10	310
61372	SALIVARY STUDY (R)	\$223.10	253
61373	GASTRO-OESOPHAGEAL REFLUX STUDY, including delayed imaging on a separate occasion when undertaken (R)	\$489.70	890
61376	OESOPHAGEAL CLEARANCE STUDY (R)	\$143.35	401
61381	GASTRIC EMPTYING STUDY, using single tracer (R)	\$574.35	4 277
61383	COMBINED SOLID AND LIQUID GASTRIC EMPTYING STUDY using dual isotope technique or the same isotope on separate days (R)	\$624.95	704
61384	RADIONUCLIDE COLONIC TRANSIT STUDY (R)	\$687.70	1468
61386	RENAL STUDY, including perfusion and renogram images and computer analysis OR cortical study with planar imaging (R)	\$332.50	4 007
61387	RENAL CORTICAL STUDY, with single photon emission tomography and planar quantification (R)	\$430.75	1 570
61389	SINGLE RENAL STUDY with pre-procedural administration of a diuretic or angiotensin converting enzyme (ACE) inhibitor (R)	\$370.55	918
61390	RENAL STUDY with diuretic administration following a baseline study (R)	\$409.95	5 537
61393	COMBINED EXAMINATION INVOLVING A RENAL STUDY following angiotensin converting enzyme (ACE) inhibitor provocation and a baseline study, in either order and related to a single referral episode (R)	\$605.50	188
61397	CYSTOURETEROGRAM (R)	\$246.85	180
61402	CEREBRAL PERFUSION STUDY, with single photon emission tomography and with planar imaging when undertaken (R)	\$605.05	5 884
61413	CEREBRO-SPINAL FLUID SHUNT PATENCY STUDY (R)	\$225.95	162
61421	BONE STUDY - whole body, with, when undertaken, blood flow, blood pool and delayed imaging on a separate occasion (R)	\$479.80	32 237
61425	BONE STUDY - whole body and single photon emission tomography, with, when undertaken, blood flow, blood pool and delayed imaging on a separate occasion (R)	\$600.70	96 680
61426	WHOLE BODY STUDY using iodine. (R)	\$554.80	1977
61429	WHOLE BODY STUDY using gallium (R)	\$543.00	188
61430	WHOLE BODY STUDY using gallium, with single photon emission tomography (R)	\$659.45	754
61433	WHOLE BODY STUDY using cells labelled with technetium (R)	\$496.95	120
61434	WHOLE BODY STUDY using cells labelled with technetium, with single photon emission tomography (R)	\$615.40	489
61429	WHOLE BODY STUDY using gallium (R)	\$543.00	188



Item	Item descriptor	Schedule fee	Services FY 2014–15
61441	BONE MARROW STUDY - whole body using technetium labelled bone marrow agents (R)	\$489.70	366
61442	WHOLE BODY STUDY, using gallium - with single photon emission tomography of 2 or more body regions acquired separately (R)	\$752.35	461
61445	BONE MARROW STUDY - localised using technetium labelled agent (R)	\$286.80	263
61446	LOCALISED BONE OR JOINT STUDY, including when undertaken, blood flow, blood pool and repeat imaging on a separate occasion (R)	\$333.55	8 000
61449	LOCALISED BONE OR JOINT STUDY and single photon emission tomography, including when undertaken, blood flow, blood pool and imaging on a separate occasion (R)	456.20	40 562
61450	LOCALISED STUDY using gallium (R)	\$397.55	252
61453	LOCALISED STUDY using gallium, with single photon emission tomography (R)	\$514.70	883
61454	LOCALISED STUDY using cells labelled with technetium (R)	\$348.10	212
61457	LOCALISED STUDY using cells labelled with technetium, with single photon emission tomography (R)	\$470.45	516
61469	LYMPHOSCINTIGRAPHY (R)	\$348.10	13 686
61495	TEAR DUCT STUDY (R)	\$223.10	386
61499	PARTICLE PERFUSION STUDY (intra-arterial) or Le Veen shunt study (R)	\$253.00	520
61650*	LEUKOSCAN STUDY, for use in diagnostic imaging of the long bones and feet in patients with suspected osteomyelitis, and where patients do not have access to <u>ex-vivo WBC scanning</u> . (R) <i>Note</i> LeukoScan is only indicated for diagnostic imaging in patients suspected of infection in the long bones and feet, including those with diabetic ulcers. The descriptor does not cover patients who are being investigated for other sites of infection.	\$878.70	219

\* The Committee regards this test to be of low clinical value, but it is used in rural settings where there is no access to the preferred test, white blood cell scanning. Its deletion from the MBS would therefore disadvantage regional and rural Australians.



## 2. Recommendations to other committees

The Committee has also developed provisional recommendations for the consideration of other committees.

### 2.1 Recommendations for referral to MSAC

During the course of the Review the Committee has made the following recommendations to MSAC.

#### 2.1.1 Item 61369—Indium-labelled octreotide study (Section 4.2 of the report)

- △ The Committee has recommended replacing this test with a PET item utilising <sup>68</sup>Ga Dotatate, and amending the item descriptor by substituting this <sup>68</sup>Ga Dotatate or a generic term such as ‘somatostatin-receptor scintigraphy’ for indium-111 octreotide.
- △ MSAC has endorsed the substitution of <sup>68</sup>Ga Dotatate for indium-111 octreotide in item 61369 following receipt of advice from the TGA about the manufacture and availability of <sup>68</sup>Ga Dotatate in Australia.
- △ The TGA’s advice to MSAC was that a <sup>68</sup>Ga generator could be granted an exemption from listing on the ARTG, including exemption from GMP, with the manufacture of <sup>68</sup>Ga Dotatate treated in a similar way to the extemporaneous compounding provisions that relate to other medicines, with individual practices taking responsibility for all aspects the product, from clinical use to quality control.
- △ The Committee notes that a new item for <sup>68</sup>Ga Dotatate PET (item 61647) was introduced into the MBS on 1 May 2018.

#### 2.1.2 Item 35404—Dosimetry, handling and injection of SIR-spheres (Section 4.6 of the report)

- △ The Committee has recommended expansion of the patient population for this item, to include other cancer types and chemotherapy regimens for which selective internal radiation therapy (SIRT) has clinical evidence of effectiveness, including metastatic colorectal cancer, NETs, other liver dominant tumours (e.g. breast cancer), cholangiocarcinoma and hepatocellular carcinoma (HCC).
- △ At the time of the Committee’s review, a contracted assessment of SIR-sphere items (35404, 35406 and 35408) was being undertaken for an MSAC review, following publication of the results of the SIRFLOX study [24]. However, as this assessment was restricted to colorectal cancer, the Committee recommended this be expanded to consider the wider range of cancers in which SIRT had clinical evidence of effectiveness.
- △ The Department subsequently consulted with the sponsor, SIRTEX, which has agreed to an expanded MSAC assessment of SIRT covering the following indications: metastatic colorectal cancer, NETs, liver dominant tumours (including breast cancer), cholangiocarcinoma and HCC.
- △ The sponsor’s application was considered by the PICO Advisory Sub-committee (PASC) at their April 2017 meeting but is currently listed on the MSAC website as ON HOLD.



### 2.1.3 MBS PET items (Section 4.4 of the report)

- △ Currently, many Australian patients, especially those with less common cancers, are disadvantaged by being unable to access MBS-rebated PET scans.
- △ The Committee therefore has recommended a modernisation of the Schedule with respect to PET items, to bring it in line with UK and US guidelines and current evidence. Its key recommendations are that:
  - the indications (cancer types) for Medicare-funded PET services be expanded to include all fluorodeoxyglucose (FDG)-avid solid tumours
  - accompanying this change, all existing MBS PET items be consolidated into four items, covering diagnosis, staging, response assessment and recurrence (re-staging) for all fluorodeoxyglucose (FDG)-avid tumours.
- △ The Oncology Clinical Committee's (OCC) recommendations with respect to FDG PET/CT items are closely aligned with those of the Committee. If implemented, these recommendations will considerably expand in the patient population eligible to receive PET scans on the MBS, but provide greater equity of access to PET for Australians affected by cancer.
- △ The Committee acknowledges that the MBS Review is a finite process and implementation of many of its recommendations will necessarily involve processes outside its lifespan. Therefore, it recommends that DICC and OCC work together in establishing a cross-professional committee to develop an MSAC submission in support of the overhaul.

## 3. Referrals from other committees

### 3.1 Referral from the Endocrine Clinical Committee (ECC)

#### 3.1.1 Item 12201– administration of thyrotropin alfa-rc

- △ The Endocrine Clinical Committee (ECC) has reviewed item 12201 and recommended that the descriptor be amended to make nuclear medicine item 61426 (Whole body study using iodine) optional rather than obligatory, changing the descriptor to:
  - Administration, by a specialist or consultant physician in the practice of his or her specialty, of thyrotropin alfa-rch (recombinant human thyroid-stimulating hormone), and arranging diagnostic imaging as necessary and pathology services under item 66650 [34].
- △ The Committee has acknowledged that the ECC's recommendation to remove the requirement for a mandatory nuclear scan after thyrotropin administration is based on practice guidelines [35] and does not, in principle, object to this recommendation. By removing the compulsion for the patient to have item 61426 after thyrotropin, patients may avoid unnecessary radiation exposure.
- △ The Committee notes, however, that some patients will be disadvantaged if the ECC's recommendation is adopted, but the restriction of claiming only one 12201 item per 12-month period remains in the descriptor. This is because patients who have a positive thyrotropin blood test will often then require a whole-body iodine scan (61426) but will not be eligible to claim the cost of a second course of thyrotropin before this.





- △ While the ECC did not make a formal recommendation, it also noted that the descriptor of item 12201 could be amended to remove some restrictions on access, and referred this to the Committee:
  - The Committee noted that although the item should have restrictions to ensure that only the appropriate patients receive services under this item, the current indications could be reduced to allow access to a wider patient group. This decision would require an extensive review of the existing guidelines, literature and data, including an appropriate cost–benefit analysis of the outcomes. The Committee noted that the Nuclear Medicine Working Group may wish to review this item, and that a process should perhaps be created to conduct such a review, if the working group agrees it is necessary [34].
- △ The Committee considered this referral, agreeing that patients currently need to go through unnecessary hurdles to access thyrotropin and that the descriptor of item 12201 could be amended to allow easier patient access. However, the Committee believes that responsibility for review of this item falls primarily within the remit of the ECC. In light of the fact the ECC has not made any specific recommendations regarding item 12201 in its final report, the Committee has also declined to make any formal recommendations regarding this item.

## 3.2 Referral from nuclear medicine specialist practitioners

### 3.2.1 Ischaemic Cardiomyopathy

- △ The Committee noted that FDG PET had originally been included in the Commonwealth PET data collection indications for *assessment of myocardial viability in patients being considered for coronary revascularisation*. Following a systematic review and economic evaluation performed in 2010, the MSAC decided not to recommend FDG PET for patients with chronic CAD and left ventricular dysfunction.
- △ A systematic review published in 2005 demonstrated the diagnostic superiority of FDG PET over SPECT MPS and echocardiography in patients with ischaemic cardiomyopathy, and concluded that *‘In patients with severe LV dysfunction, that are deemed to have no viable myocardium or indeterminate results in assessments using other non-invasive tests, PET may have a role in further identifying patients who may benefit from revascularization.’* The authors of this review were unable to draw firm conclusions on the impact of PET viability assessment on long-term clinical outcomes in patients with severe left ventricular dysfunction [36].
- △ A recent comprehensive review of the cost-effectiveness of FDG PET in ischaemic cardiomyopathy, undertaken by the National Institute for Health Research in the United Kingdom, has also demonstrated that PET performs well in this clinical setting and is able to accurately predict functional recovery following revascularisation.[37] While contrast-enhanced MRI (CE MRI) was the most cost-effective investigation overall, FDG PET performed comparably in most clinical scenarios and demonstrated higher specificity than CE MRI for predicting recovery following revascularisation. Furthermore, FDG PET demonstrated superior diagnostic performance to SPECT MPS and dobutamine SE in this group of patients.
- △ In the PARR-2 trial, patients randomised to have PET-directed care of suspected ischaemic cardiomyopathy had slightly lower mortality than those who received ‘standard’ care (which included other forms of viability assessment) [38]; this





difference was highly significant in a large centre where PET was readily available and integrated into clinical management, when postoperative adverse events were reduced by more than 50% [39].

- △ In the recently published STICHES study (Velazquez 2016), coronary bypass surgery resulted in improved cardiovascular and all-cause mortality, and reduced hospitalisations, compared to medical therapy in patients with ischaemic cardiomyopathy over a median 10-year period of follow-up [40]. Short-term mortality in the surgical arm, however, was three times higher than in patients treated medically,[41] indicating a potential role for preoperative imaging to avoid futile surgery in patients unlikely to benefit from revascularisation. Functional imaging had not proved useful to predict successful outcomes in the original STICH study; [41] however, the Committee noted that this had generally consisted of MPS or SE, modalities known to be associated with lower predictive accuracy compared to CE MRI or FDG PET.
- △ The Committee considered whether MSAC should re-examine the funding of FDG PET for assessment of myocardial viability, noting that CE MRI may be sufficient in the majority of patients. The Committee was advised that MSAC had declined to approve CE MRI for this indication and, hence, was highly unlikely to favourably consider an application to approve FDG PET. Following receipt of this advice, the Committee decided against recommending referral of this issue to MSAC.

### 3.2.2 Cardiac Sarcoidosis

- △ Sarcoidosis is an idiopathic condition characterised by non-caseating, granulomatous inflammation. Cardiac sarcoidosis can result in left ventricular dysfunction and ventricular arrhythmias, and has a high mortality rate if left untreated. There has been a recent increase in cardiac sarcoidosis diagnoses in western countries. The main tests used in suspected cardiac sarcoidosis are CE MRI and FDG PET, although other clinical features are also used to establish the diagnosis. The treatment of cardiac sarcoidosis is high-dose steroid therapy, which can restore normal left ventricular function in a significant number of patients but which can be associated with major side effects.
- △ FDG PET has a role in this condition, both for confirming the diagnosis in uncertain cases, and for documenting the response to therapy. FDG PET has been recommended for the evaluation and monitoring of patients with suspected cardiac sarcoidosis in the expert consensus statement recently published by the Heart Rhythm Society [42], and the joint statement from the Society of Nuclear Medicine and Molecular Imaging and American Society of Nuclear Cardiology [43].
- △ The Committee discussed whether MSAC should consider the funding of FDG PET for the diagnosis and therapeutic monitoring of patients with cardiac sarcoidosis, noting that CE MRI may be sufficient in some patients. Following receipt of advice that MSAC had recently rejected an application for funding of MRI in cardiomyopathy, and that any application for the use of FDG PET in the same situation would be unlikely to succeed, the Committee decided against recommending referral of this issue to MSAC.



## 5. Impact statement

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The recommendations detailed in this report serve to positively impact both patients and providers alike. They aim to modernise the portion of the MBS associated with nuclear medicine services as well as improving the safety, quality and appropriateness of services provided.

Recommendations relating to the creation of new items are based upon an established clinical need. These recommendations reflect services which are considered contemporary best practice and seek to improve the provision of future diagnostic and therapeutic services for patients.

Recommendations relating to the deletion of items from the MBS serve to simplify and streamline the Schedule through the removal of items that are considered obsolete. Recommendations to delete reference to specific imaging techniques reflect outdated imaging technology being superseded by newer techniques.

The Committee's recommendation to overhaul MBS items relating to services for PET, serve to positively impact Australians through the expansion of access to PET services for patients with cancer not currently covered by the MBS. Examples include FDG-avid cancers such as pancreatic, thyroid, gastric and breast cancer. Consumers stand to benefit from greater equity of access to PET services, bringing Australia's PET funding indications into line with those in other developed countries, such as the USA and the UK.

Some of the recommendations seek to increase the Schedule fee associated with items. These recommendations are aimed at ensuring equitable Medicare rebates for nuclear medicine tests and procedures. These recommendations may also lead to reduced out-of-pocket costs to consumers.

Overall, the recommendations are expected to benefit patients by ensuring improved access to nuclear medicine services. They are expected to benefit providers through a more streamlined and modern Schedule with more equitable fees that better reflect the service being provided.



## 6. References

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## 7. Glossary

Term	Description
AANMS	Australasian Association of Nuclear Medicine Specialists
ABS	Australian Bureau of Statistics
ANSTO	Australian Nuclear Science and Technology Organisation
ARTG	Australian Register of Therapeutic Goods
CAGR	Compound annual growth rate, or the average annual growth rate over a specified time period.
Change	When referring to an item, describes when the item and/or its services will be affected by the recommendations. This could result from a range of recommendations, such as: (i) specific recommendations that affect the services provided by changing item descriptors or explanatory notes, (ii) the consolidation of item numbers, and (iii) splitting item numbers (e.g. splitting the current services provided across two or more items).
CSCC	Cardiac Services Clinical Committee
Department, The	Australian Government Department of Health
Delete	Describes when an item is recommended for removal from the MBS and its services will no longer be provided under the MBS.
DHS	Australian Government Department of Human Services
ECC	Endocrine Clinical Committee
FDG	Fluorodeoxyglucose, a radiopharmaceutical used in PET imaging
FY	Financial year
GP	General practitioner
High-value care	Services of proven efficacy reflecting current best medical practice, or for which the potential benefit to consumers exceeds the risk and costs.



Inappropriate use / misuse	The use of MBS services for purposes other than those intended. This includes a range of behaviours, from failing to adhere to particular item descriptors or rules through to deliberate fraud.
Low-value care	Services that evidence suggests confer no, or very little, benefit to consumers, or for which the risk of harm exceeds the likely benefit, or, more broadly, where the added costs of services do not provide proportional added benefits.
MBS	Medicare Benefits Schedule
MBS item	An administrative object listed in the MBS and used for the purposes of claiming and paying Medicare benefits, consisting of an item number, service descriptor and supporting information, schedule fee and Medicare benefits.
MBS service	The actual medical consultation, procedure or test to which the relevant MBS item refers.
Misuse (of MBS item)	The use of MBS services for purposes other than those intended. This includes a range of behaviours, from failing to adhere to particular item descriptors or rules through to deliberate fraud.
MPS	Myocardial perfusion scan
MSAC	Medical Services Advisory Committee
NETs	Neuroendocrine tumours
No change or unchanged	Describes when the services provided under these items will not be changed or affected by the recommendations. This does not rule out small changes in item descriptors (e.g. references to other items, which may have changed as a result of the MBS Review or prior reviews).
Obsolete services	Services that should no longer be provided, as they do not represent current clinical best practice and have been superseded by superior tests or procedures.
OCC	Oncology Clinical Committee
PBS	Pharmaceutical Benefits Scheme
Planar imaging	An imaging technique which produces a 2-dimensional image
PET	Positron emission tomography
Radiopharmaceutical	A pharmaceutical containing a radioisotope used for diagnosis or therapy
Services average annual growth	The average growth per year, over 5 years to 2014/15, in utilisation of services. Also known as the compound annual growth rate (CAGR).





SIRT	Selective internal radiation therapy
SPECT	Single-photon emission computed tomography
TGA	Therapeutic Goods Administration
The Committee	The Committee
The Taskforce	The MBS Review Taskforce
Total benefits	Total benefits paid in 2014/15 unless otherwise specified.

## Appendix A Summary for consumers

This table describes the medical service, the recommendations of the clinical experts and why the recommendations have been made.

### **Recommendation 1:** *All MBS nuclear medicine cardiac items (10 in total).*

Item	What it does	Committee recommendation	What would be different	Why
All MBS nuclear medicine cardiac items (10 in total).	A range of imaging tests to investigate heart function and help diagnose coronary heart disease.	To simplify the Schedule by reducing the number of cardiac items and consolidating them into just 5 relevant items. To remove tests that used outdated scanning technology.	Replace older tests with better tests with less impact on the body are available.	Simplifying the Schedule will make tests available that better reflect current practice.
61303	A myocardial perfusion scan (MPS) is a test that is used to look for major blockages to the blood supply of the heart, commonly known as coronary artery disease.	1. To split this item to make two different items with different fees: one for testing at rest and another for testing when the heart is stressed (usually during exercise such as on a treadmill). 2 add to this item a stress electrocardiogram (ECG) test. 3 Remove referencing to the type of imaging technology.	There should be minimal impact on consumers.	It costs less to conduct rest test than it does the stress test and currently, with them being the same item, they are paid at the same fee.

### **Recommendation 2:** *Amend the descriptor for item 61369 to replace this test with a PET item utilising the radiopharmaceutical gallium-68 (<sup>68</sup>Ga) Dotatate.*

Item	What it does	Committee recommendation	What would be different	Why
61369	An imaging test for diagnosis of gastro-entero-pancreatic endocrine tumour (cancer).	The test be replaced by a new test using positron emission tomography (PET) imaging and a different radiopharmaceutical (gallium-68 dotatate).	Consumers would have access to a superior test at lower cost.	The test using gallium-68 dotatate is a more sensitive test and can be delivered at lower cost

**Recommendation 3:** *All MBS PET items require a significant overhaul, consistent with UK and US guidelines.*

Items	What they do	Committee recommendation	What would be different	Why
All MBS PET items	Positron emission tomography (PET) scans are a nuclear medicine scans that can provide imaging of chemical functions occurring within the body. PET scans are particularly useful for detecting and monitoring cancers and dementia.	<p>That all PET items on the Medicare Schedule be overhauled, replacing the 20 current items with 4 items covering:</p> <ul style="list-style-type: none"><li>• diagnosis</li><li>• assessment of stage of cancer</li><li>• assessment of treatment response</li><li>• suspected residual or recurrent cancer.</li></ul> <p>These will cover all cancers known to take up FDG, the radioactive tracer used in PET scans.</p>	All patients with cancers known to take up the radioactive tracer FDG, including pancreatic cancer and recurrent breast cancer, would be eligible to get their scans done on Medicare.	The MBS PET items have not been updated for many years. This means that many Australian patients, especially those with less common cancers, are currently unable to get PET scans on Medicare, putting them at a disadvantage compared with people whose cancers are currently covered.

**Recommendation 4:** *Include in the Explanatory Notes of the MBS, a specific statement outlining those situations where co-claiming of diagnostic CECT with Positron emission tomography (PET) scans is considered inappropriate.*

Items	What they do	Committee recommendation	What would be different	Why
All MBS PET items	Positron emission tomography (PET) scans are a nuclear medicine scans that can provide imaging of chemical functions occurring within the body. PET scans are particularly useful for detecting and monitoring cancers and dementia.	The Committee agreed that it is inappropriate to request CECT together with a PET scan; that it is inappropriate for a practice to perform a default CECT with a PET scan unless specifically requested, or when CECT has recently been performed.	All patients with cancers known to take up the radioactive tracer FDG, including pancreatic cancer and recurrent breast cancer, would be eligible to get their scans done on Medicare.	PET/CT is now routinely performed in Australia for anatomical localisation and planning of cancer treatment. Combined PET/CT has proven advantages over stand-alone PET in terms of diagnostic accuracy and certainty. Combined PET/CT can eliminate the need for CECT procedures in some cancer types, but is still needed in particular cancer types, particularly pelvic or neck.

**Recommendation 5:** *New PET item <sup>68</sup>Ga-PMSA PET/CT for patients with prostate cancer.*

Items	What they do	Committee recommendation	What would be different	Why
New PET item <sup>68</sup> Ga-PMSA PET/CT	This is a new, very accurate scan to detect prostate cancer.	For MSAC to consider a new item include in the MBS schedule instructions outlining when and when it is not appropriate for a patient to receive both a contrast enhanced-CT scan (CECT) and a PET scan.	If this scan became available on Medicare more people with prostate cancer would be able to receive this scan.	This new scan is already being used in Australia but only those people who can afford to pay for it privately can get it.

**Recommendation 6:** *Therapeutic nuclear medicine items.*

Items	What they do	Committee recommendation	What would be different	Why
16003,16006,16009, 16012,16015,16018	A range of nuclear medicine (NM) tests that use radiopharmaceuticals (drugs containing radioactive materials) to treat rather than diagnose diseases and conditions, such as cancer.	To move radiopharmaceuticals to the PBS or increase the MBS fees for existing therapeutic NM items, as the current fees have not been updated for some time and are often less than the cost of the radiopharmaceutical. Currently NM providers can only offer these treatments at a loss, meaning the treatments are not offered at all or only in public hospitals.	Moving the radiopharmaceuticals to the PBS or increasing the fees would mean that more NM providers would be able to offer these treatments to people on Medicare.	Patients are currently disadvantaged because they are not eligible to receive many of these treatments under Medicare. An example is Radium-223 for prostate cancer.

**Recommendation 7:** *New therapeutic nuclear medicine item LU-177 octreotate to be registered with TGA.*

Items	What they do	Committee recommendation	What would be different	Why
New Medicare or PBS item LU-177 octreotate	Nuclear medicine (NM) tests that use radiopharmaceuticals (drugs containing radioactive materials) to treat rather than diagnose diseases and conditions, such as cancer.	That the Department of Health pursue registration of Lu-177 octreotate for rare, inoperable neuroendocrine tumours with a view to registering with PBS or creating a new Medicare item in the future.	Registration of and listing of Lu-177 octreotate would allow Australian people with neuroendocrine tumours to receive the new treatment under Medicare.	People are currently unable to receive this new cancer treatment in Australia.

**Recommendation 8:** *Expand the patient population for Interventional radiology procedure — SIR-spheres for selective internal radiation of hepatic tumours.*

Item	What it does	Committee recommendation	What would be different	Why
35404	A treatment for inoperable liver cancer that delivers millions of tiny radioactive beads directly to the tumours. These tumours may have started in the liver (primary liver cancer) or have spread to the liver from another part of the body (metastases).	To expand the range of cancers for which this treatment can be given under Medicare. Currently MBS funding is restricted only to treatment of patients with liver metastases from colorectal cancer.	Patients with certain other cancers that have spread to the liver, not only those with metastatic colorectal cancer, would be eligible to receive this treatment on Medicare.	There is now evidence to show that this treatment can assist patients with breast cancer that has spread to the liver, neuroendocrine tumours, primary liver cancer and bile duct cancer, but patients with these cancers are currently disadvantaged because they are not eligible to receive this treatment under Medicare.

**Recommendation 9:** *Removal of obsolete MBS nuclear medicine non-imaging items.*

Items	What they do	Committee recommendation	What would be different	Why
12503, 12506, 12509, 12512, 12515, 12518, 12521, 12530	A range of nuclear medicines tests used to investigate iron and vitamin B12 levels, the thyroid gland and blood and protein loss.	To delete these items.	As these tests are rarely, if ever, used; the impact on consumers should be minimal.	These tests are obsolete and no longer ordered by doctors. There are better tests now available.

**Recommendation 10:** *Update descriptors of MBS nuclear medicine lung items to remove reference to imaging technique.*

Items	What they do	Committee recommendation	What would be different	Why
61328 , 61340, 61348.	Nuclear medicines tests for examining the lungs.	To include in the explanatory notes of the Medicare Schedule advice on when it is appropriate to use these tests in the case of suspected pulmonary embolism (blood clot in the blood vessels of the lung) and deep vein thrombosis (DVT).	There should be no change to the way the study is performed.	For many people these scans are unnecessary. The new notes provide instruction to doctors on when they should order these tests.

**Recommendations 11: General nuclear medicine liver and spleen items.**

Items	What they do	Committee recommendation	What would be different	Why
61352, 61353, 61356	A nuclear medicine test for red blood cells, liver and spleen.	To delete these items with planar imaging and update others to reflect best practice.	Delete tests with obsolete imaging practices and update items 6135 and 61356 to remove reference to imaging technology.	These tests are obsolete and no longer ordered by doctors. There are better tests now available. By removing references to specific imaging modality, MBS does not need to be updated as improvements in technology occur

**Recommendation 12: General nuclear medicine hepatobiliary items.**

Items	What they do	Committee recommendation	What would be different	Why
61360,61361	A nuclear medicine test for examining the liver and gall bladder.	To remove reference in the explanatory notes of the Medicare Schedule to a commercial product that is no longer available.	There will be no impact the way the study is conducted as this is an administrative change.	To update the Schedule to reflect current practice.

**Recommendations 13, 14, 16, 17: Testicular study, Cerebro-spinal fluid transport study, blood flow studies - nuclear medicine general imaging items.**

Items	What they do	Committee recommendation	What would be different	Why
61401, 61405, 61417, 61437, 61438,61458, 61461	A range of imaging tests for cancer of the testicles and brain, and tests for blood flow.	To delete these items.	These tests have been replaced with newer technology tests.	These tests are obsolete and no longer ordered by doctors. There are better tests now available.

**Recommendation 15: Cerebro-spinal fluid transport study.**

Items	What they do	Committee recommendation	What would be different	Why
61409	A nuclear medicine scan for hydrocephalus (accumulation of cerebrospinal fluid (CSF) within the brain).	To increase the fee to adequately cover the cost of the radiopharmaceutical.	There should be improved patient access to this scan outside of public hospitals.	The current fee is inadequate to cover the cost of the materials used in the scan. This discourages private nuclear medicine practices from performing the scan.

**Recommendation 18:** *Repeat planar and SPECT imaging where the previous scan was abnormal or equivocal.*

Items	What they do	Committee recommendation	What would be different	Why
61462	A repeat nuclear medicine scan performed up to several days after the first, if the previous scan was abnormal or unclear.	To change the descriptor to remove deleted item 61484 and to refer this item for audit.	To assess the clinical need for this scan and limit access to this scan to prevent this being the first scan performed.	These are necessary administrative changes to prevent inappropriate co-claiming.

**Recommendation 19:** *Thyroid study.*

Items	What they do	Committee recommendation	What would be different	Why
61473	A nuclear medicine scan of the thyroid gland.	To simplify the item descriptor.	There should be no impact on the way the study is conducted.	This is an administrative change which should double claiming with item 12518.

**Recommendation 20:** *Parathyroid study.*

Items	What they do	Committee recommendation	What would be different	Why
61480	A nuclear medicine scan of the parathyroid gland.	To simplify the item descriptor and remove reference to the imaging modality.	There should be no impact on the way the study is conducted.	This is an administrative change which should not impact how the study is performed.

**Recommendation 21:** *Adrenal studies.*

Items	What they do	Committee recommendation	What would be different	Why
61484 61485	Nuclear medicine scans of the adrenal glands.	To delete item 61484 and to increase the fee of item 61485 to cover the cost of the radiopharmaceutical.	There should be improved patient access to item 61485 outside of public hospitals.	Item 6184 is an obsolete scan. The current fee for item 61485 is inadequate to cover the cost of the materials used in the scan. This discourages private nuclear medicine practices from performing the scan.

**Recommendation 22:** *CT scan performed with SPECT for anatomic localisation/attenuation correction.*

Items	What they do	Committee recommendation	What would be different	Why
61505	A CT scan used alongside a nuclear medicine scan to improve localisation and hence the accuracy of the nuclear medicine scan.	To amend the descriptor of this item to cover the same body area and allow this item to be claimed with both SPECT and PET scans.	This item cannot be claimed with 61505 (Bone Study).	Combined CT and PET should be used for accurately determining where disease is located in the body.





## Appendix B Recommendations list

### Nuclear medicine imaging items including cardiac and PET items

Item	Current descriptor	Recommendation	Section reference
61302	SINGLE STRESS OR REST MYOCARDIAL PERFUSION STUDY - planar imaging.	Delete	4.1
61303	SINGLE STRESS OR REST MYOCARDIAL PERFUSION STUDY - with single photon emission tomography and with planar imaging when undertaken.	Change	4.1
61306	COMBINED STRESS AND REST, stress and re-injection or rest and redistribution myocardial perfusion study, including delayed imaging or re-injection protocol on a subsequent occasion - planar imaging.	Delete	4.1
61307	COMBINED STRESS AND REST, stress and re-injection or rest and redistribution myocardial perfusion study, including delayed imaging or re-injection protocol on a subsequent occasion - with single photon emission tomography and with planar imaging when undertaken.	Change	4.1
61310	MYOCARDIAL INFARCT-AVID-STUDY, with planar imaging and single photon emission tomography, OR planar imaging or single photon emission tomography.	Change	4.1
61313	GATED CARDIAC BLOOD POOL STUDY, (equilibrium), with planar imaging and single photon emission tomography OR planar imaging or single photon emission tomography.	Change	4.1
61314	GATED CARDIAC BLOOD POOL STUDY, and first pass blood flow or cardiac shunt study, with planar imaging and single photon emission tomography, OR planar imaging, or single photon emission tomography.	Change	4.1
61316	GATED CARDIAC BLOOD POOL STUDY, with intervention, with planar imaging and single photon emission tomography, OR planar imaging, or single photon emission tomography.	Consolidate	4.1
61317	GATED CARDIAC BLOOD POOL STUDY, with intervention and first pass blood flow study or cardiac shunt study, with planar imaging and single photon emission tomography OR planar imaging, or single photon emission tomography.	Consolidate	4.1
61320	CARDIAC FIRST PASS BLOOD FLOW STUDY OR CARDIAC SHUNT STUDY, not being a service to which another item in this Group applies.	Consolidate	4.1
61328	LUNG PERFUSION STUDY, with planar imaging and single photon emission tomography OR planar imaging, or single photon emission tomography. (R)	Change	4.8
61340	LUNG VENTILATION STUDY using aerosol, technegas or xenon gas, with planar imaging and single photon emission tomography OR planar imaging or single photon emission tomography. (R)	Change	4.8
61348	LUNG PERFUSION STUDY AND LUNG VENTILATION STUDY using aerosol, technegas or xenon gas, with planar imaging and single photon emission tomography, OR planar imaging, or single photon emission tomography. (R)	Change	4.8
61352	LIVER AND SPLEEN STUDY (colloid) - planar imaging. (R)	Delete	4.9



Item	Current descriptor	Recommendation	Section reference
61353	LIVER AND SPLEEN STUDY (colloid), with single photon emission tomography and with planar imaging when undertaken. (R)	Change	4.9
61356	RED BLOOD CELL SPLEEN OR LIVER STUDY, including single photon emission tomography when undertaken. (R)	Change	4.9
61360	HEPATOBIILIARY STUDY, including morphine administration or pre-treatment with a cholagogue when performed. (R)	Change	4.10
61361	HEPATOBIILIARY STUDY with formal quantification following baseline imaging, using a cholagogue. (R)	Change	4.10
61364	BOWEL HAEMORRHAGE STUDY. (R)	No change	4.21
61368	MECKEL'S DIVERTICULUM STUDY. (R)	No change	4.21
61369	INDIUM-LABELLED OCTREOTIDE STUDY - including single photon emission tomography when undertaken, where: (a) there is a suspected gastro-entero-pancreatic endocrine tumour, based on biochemical evidence, with negative or equivocal conventional imaging; or (b) a surgically amenable gastro-entero-pancreatic endocrine tumour has been identified based on conventional techniques, in order to exclude additional disease sites. (R)	Change	4.2
61372	SALIVARY STUDY. (R)	No change	4.21
61373	GASTRO-OESOPHAGEAL REFLUX STUDY, including delayed imaging on a separate occasion when undertaken. (R)	No change	4.21
61376	OESOPHAGEAL CLEARANCE STUDY. (R)	No change	4.21
61381	GASTRIC EMPTYING STUDY, using single tracer. (R)	No change	4.21
61383	COMBINED SOLID AND LIQUID GASTRIC EMPTYING STUDY using dual isotope technique or the same isotope on separate days. (R)	No change	4.21
61384	RADIONUCLIDE COLONIC TRANSIT STUDY. (R)	No change	4.21
61386	RENAL STUDY, including perfusion and renogram images and computer analysis OR cortical study with planar imaging. (R)	No change	4.21
61387	RENAL CORTICAL STUDY, with single photon emission tomography and planar quantification. (R)	No change	4.21
61389	SINGLE RENAL STUDY with pre-procedural administration of a diuretic or angiotensin converting enzyme (ACE) inhibitor. (R)	No change	4.21
61390	RENAL STUDY with diuretic administration following a baseline study. (R)	No change	4.21
61393	COMBINED EXAMINATION INVOLVING A RENAL STUDY following angiotensin converting enzyme (ACE) inhibitor provocation and a baseline study, in either order and related to a single referral episode. (R)	No change	4.21
61397	CYSTOURETEROGRAM. (R)	No change	4.21
61401	TESTICULAR STUDY. (R)	Delete	4.11



Item	Current descriptor	Recommendation	Section reference
61402	CEREBRAL PERFUSION STUDY, with single photon emission tomography and with planar imaging when undertaken. (R)	No change	4.21
61405	BRAIN STUDY WITH BLOOD BRAIN BARRIER AGENT, with planar imaging and single photon emission tomography, OR planar imaging, or single photon emission tomography. (R)	Delete	4.12
61409	CEREBRO-SPINAL FLUID TRANSPORT STUDY, with imaging on 2 or more separate occasions. (R)	Change	4.13
61413	CEREBRO-SPINAL FLUID SHUNT PATENCY STUDY. (R)	No change	4.21
61417	DYNAMIC BLOOD FLOW STUDY OR REGIONAL BLOOD VOLUME QUANTITATIVE STUDY, not being a service associated with a service to which another item in this Group applies. (R)	Delete	4.14
61421	BONE STUDY - whole body, with, when undertaken, blood flow, blood pool and delayed imaging on a separate occasion. (R)	No change	4.21
61425	BONE STUDY - whole body and single photon emission tomography, with, when undertaken, blood flow, blood pool and delayed imaging on a separate occasion. (R)	No change	4.21
61426	WHOLE BODY STUDY using iodine. (R)	No change	4.21
61429	WHOLE BODY STUDY using gallium. (R)	No change	4.21
61430	WHOLE BODY STUDY using gallium, with single photon emission tomography. (R)	No change	4.21
61433	WHOLE BODY STUDY using cells labelled with technetium. (R)	No change	4.21
61434	WHOLE BODY STUDY using cells labelled with technetium, with single photon emission tomography. (R)	No change	4.21
61437	WHOLE BODY STUDY using thallium (R)	Delete	4.15
61438	WHOLE BODY STUDY using thallium, with single photon emission tomography. (R)	No change	4.15
61441	BONE MARROW STUDY - whole body using technetium labelled bone marrow agents (R)	No change	4.21
61442	WHOLE BODY STUDY, using gallium - with single photon emission tomography of 2 or more body regions acquired separately. (R)	No change	4.21
61445	BONE MARROW STUDY - localised using technetium labelled agent. (R)	No change	4.21
61446	LOCALISED BONE OR JOINT STUDY, including when undertaken, blood flow, blood pool and repeat imaging on a separate occasion. (R)	No change	4.21
61449	LOCALISED BONE OR JOINT STUDY and single photon emission tomography, including when undertaken, blood flow, blood pool and imaging on a separate occasion. (R)	No change	4.21
61450	LOCALISED STUDY using gallium. (R)	No change	4.21
61453	LOCALISED STUDY using gallium, with single photon emission tomography. (R)	No change	4.21
61454	LOCALISED STUDY using cells labelled with technetium. (R)	No change	4.21
61457	LOCALISED STUDY using cells labelled with technetium, with single photon emission tomography (R)	No change	4.21



Item	Current descriptor	Recommendation	Section reference
61458	LOCALISED STUDY using thallium. (R)	Delete	4.15
61461	LOCALISED STUDY using thallium, with single photon emission tomography. (R)	Change	4.15
61462	REPEAT PLANAR AND SINGLE PHOTON EMISSION TOMOGRAPHY IMAGING, OR REPEAT PLANAR IMAGING OR SINGLE PHOTON EMISSION TOMOGRAPHY IMAGING on an occasion subsequent to the performance of any one of items 61364, 61426, 61429, 61430, 61442, 61450, 61453, 61469, 61484 or 61485 where there is no additional administration of radiopharmaceutical and where the previous radionuclide scan was abnormal or equivocal. (R)	Change	4.16
61469	LYMPHOSCINTIGRAPHY. (R)	No change	4.21
61473	THYROID STUDY including uptake measurement when undertaken. (R)	Change	4.17
61480	PARATHYROID STUDY, planar imaging and single photon emission tomography when undertaken. (R)	Change	4.18
61484	ADRENAL STUDY. (R)	Delete	4.19
61485	ADRENAL STUDY, with single photon emission tomography. (R)	Change	4.19
61495	TEAR DUCT STUDY. (R)	No change	4.21
61499	PARTICLE PERFUSION STUDY (intra-arterial) or Le Veen shunt study. (R)	No change	4.21
61505	CT scan performed at the same time and covering the same body area as single photon emission tomography for the purpose of anatomic localisation or attenuation correction where no separate diagnostic CT report is issued and only in association with items 61302 – 61650. (R)	Change	4.20
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)	Change	4.4
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)	Change	4.4
61538	FDG PET study of the brain for evaluation of suspected residual or recurrent malignant brain tumour based on anatomical imaging findings, after definitive therapy (or during ongoing chemotherapy) in patients who are considered suitable for further active therapy. (R)	Change	4.4
61541	Whole body FDG PET study, following initial therapy, for the evaluation of suspected residual, metastatic or recurrent colorectal carcinoma in patients considered suitable for active therapy. (R)	Change	4.4
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.	Change	4.4
61559	FDG PET study of the brain, performed for the evaluation of refractory epilepsy. (R)	Change	4.4
61565	Whole body FDG PET study, following initial therapy, performed for the evaluation of suspected residual,	Change	4.4



Item	Current descriptor	Recommendation	Section reference
	metastatic or recurrent ovarian carcinoma in patients considered suitable for active therapy. (R)		
61571	Whole body FDG PET study, for the further primary staging of patients with histologically proven carcinoma of the uterine cervix, at FIGO stage IB2 or greater by conventional staging, prior to planned radical radiation therapy or combined modality therapy with curative intent. (R)	Change	4.4
61575	Whole body FDG PET study, performed for the further staging of patients with confirmed local recurrence of carcinoma of the uterine cervix considered suitable for salvage pelvic chemoradiotherapy or pelvic exenteration with curative intent. (R)	Delete	4.4
61577	Whole body FDG PET study, performed for the staging of proven oesophageal or GEJ carcinoma. (R)	Change	4.4
61598	Whole body FDG PET study performed for the staging of biopsy-proven newly diagnosed or recurrent head and neck cancer. (R)	Change	4.4
61604	Whole body FDG PET study performed for the evaluation of patients with suspected residual head and neck cancer after definitive treatment, and who are suitable for active therapy. (R)	Change	4.4
61610	Whole body FDG PET study performed for the evaluation of metastatic squamous cell carcinoma of unknown primary site involving cervical nodes. (R)	Change	4.4
61616	Whole body FDG PET study for the initial staging of indolent non-Hodgkin's lymphoma where clinical, pathological and imaging findings indicate that the stage is I or IIA and the proposed management is definitive radiotherapy with curative intent. (R)	Change	4.4
61620	Whole body FDG PET study for the initial staging of newly diagnosed or previously untreated Hodgkin's or non-Hodgkin's lymphoma (excluding indolent non-Hodgkin's lymphoma). (R)	Change	4.4
61622	Whole body FDG PET study to assess response to first line therapy either during treatment or within three months of completing definitive first line treatment for Hodgkin's or non-Hodgkin's lymphoma (excluding indolent non-Hodgkin's lymphoma). (R)	Change	4.4
61628	Whole body FDG PET study for restaging following confirmation of recurrence of Hodgkin's or non-Hodgkin's lymphoma (excluding indolent non-Hodgkin's lymphoma). (R)	Change	4.4
61632	Whole body FDG PET study to assess response to second-line chemotherapy when stem cell transplantation is being considered, for Hodgkin's or non-Hodgkin's lymphoma (excluding indolent non-Hodgkin's lymphoma). (R)	Change	4.4
61640	Whole body FDG PET study for initial staging of patients with biopsy-proven bone or soft tissue sarcoma (excluding gastrointestinal stromal tumour) considered by conventional staging to be potentially curable. (R)	Change	4.4
61646	Whole body FDG PET study for the evaluation of patients with suspected residual or recurrent sarcoma (excluding gastrointestinal stromal tumour) after the initial course of definitive therapy to determine	Change	4.4



Item	Current descriptor	Recommendation	Section reference
	suitability for subsequent therapy with curative intent. (R)		
61650	LEUKOSCAN STUDY, for use in diagnostic imaging of the long bones and feet in patients with suspected osteomyelitis, and where patients do not have access to <i>ex-vivo WBC scanning</i> . (R) <i>Note</i> LeukoScan is only indicated for diagnostic imaging in patients suspected of infection in the long bones and feet, including those with diabetic ulcers. The descriptor does not cover patients who are being investigated for other sites of infection.	No change	4.21

### Interventional radiology procedures

Item	Current descriptor	Recommendation	Section reference
35404	DOSIMETRY, HANDLING AND INJECTION OF SIR-SPHERES for selective internal radiation therapy of hepatic metastases which are secondary to colorectal cancer and are not suitable for resection or ablation, used in combination with systemic chemotherapy using 5-fluorouracil (5FU) and leucovorin, not being a service to which item 35317, 35319, 35320 or 35321 applies The procedure must be performed by a specialist or consultant physician recognised in the specialties of nuclear medicine or radiation oncology on an admitted patient in a hospital. To be claimed once in the patient's lifetime only.	Change	4.6

### Nuclear medicine non-imaging items

Item	Current descriptor	Recommendation	Section reference
12500	BLOOD VOLUME ESTIMATION.	No change	4.7
12503	ERYTHROCYTE RADIOACTIVE UPTAKE SURVIVAL TIME TEST OR IRON KINETIC TEST.	Delete	4.7
12506	GASTROINTESTINAL BLOOD LOSS ESTIMATION involving examination of stool specimens.	Delete	4.7
12509	GASTROINTESTINAL PROTEIN LOSS.	Delete	4.7
12512	RADIOACTIVE B12 ABSORPTION TEST 1 isotope.	Delete	4.7
12515	RADIOACTIVE B12 ABSORPTION TEST 2 isotopes.	Delete	4.7
12518	THYROID UPTAKE (using probe).	Delete	4.7
12521	PERCHLORATE DISCHARGE STUDY.	Delete	4.7
12524	RENAL FUNCTION TEST (without imaging procedure).	No change	4.7
12527	RENAL FUNCTION TEST (with imaging and at least 2 blood samples).	No change	4.7
12530	WHOLE BODY COUNT not being a service associated with a service to which another item applies.	Delete	4.7
12533	CARBON-LABELLED UREA BREATH TEST using oral C-13 or C-14 urea, performed by a specialist or consultant physician, including the measurement of exhaled <sup>13</sup> CO <sub>2</sub> or <sup>14</sup> CO <sub>2</sub> , for either:- (a) the confirmation of <i>Helicobacter pylori</i> colonisation, OR	No change	4.7



Item	Current descriptor	Recommendation	Section reference
	(b) the monitoring of the success of eradication of <i>Helicobacter pylori</i> . not being a service to which 66900 applies.		

#### Therapeutic nuclear medicine items

Item	Current descriptor	Recommendation	Section reference
16003	INTRACAVITY ADMINISTRATION OF A THERAPEUTIC DOSE OF YTTRIUM 90 not including preliminary paracentesis, not being a service associated with selective internal radiation therapy or to which item 35404, 35406 or 35408 applies.	Change	4.5
16006	ADMINISTRATION OF A THERAPEUTIC DOSE OF IODINE 131 for thyroid cancer by single dose technique.	Change	4.5
16009	ADMINISTRATION OF A THERAPEUTIC DOSE OF IODINE 131 for thyrotoxicosis by single dose technique.	Change	4.5
16012	INTRAVENOUS ADMINISTRATION OF A THERAPEUTIC DOSE OF PHOSPHOROUS 32	Change	4.5
16015	ADMINISTRATION OF STRONTIUM 89 for painful bony metastases from carcinoma of the prostate where hormone therapy has failed and either: (i) the disease is poorly controlled by conventional radiotherapy; or (ii) conventional radiotherapy is inappropriate, due to the wide distribution of sites of bone pain.	Change	4.5
16018	ADMINISTRATION OF <sup>153</sup> SM-LEXIDRONAM for the relief of bone pain due to skeletal metastases (as indicated by a positive bone scan) where hormonal therapy and/or chemotherapy have failed and either the disease is poorly controlled by conventional radiotherapy or conventional radiotherapy is inappropriate, due to the wide distribution of sites of bone pain.	Change	4.5





## Appendix C Proposed new items

### List of new items with recommendations

Item	Descriptor	Recommendation	Section reference
New split 61303A	<p>Item 61303A Single stress myocardial perfusion study, performed for:</p> <ul style="list-style-type: none"> <li>(a) Evaluation of symptoms possibly related to cardiac ischaemia</li> <li>(b) Assessment of functional severity of known CAD</li> <li>(c) Pre-operative assessment of a patient at intermediate or high risk of CAD</li> </ul> <p>Not claimable for (i) screening; or (ii) patients who are asymptomatic and have a normal cardiac examination; A myocardial perfusion study is claimable no more than once every 12 months in the absence of significant symptom evolution and/or revascularisation.</p> <p>Including:</p> <ul style="list-style-type: none"> <li>(a) Exercise or pharmacological stress; and</li> <li>(b) Multi-channel ECG monitoring and recording; and</li> <li>(b) The performance of the study as per current recommendations of the CSANZ. <p>Fee: \$658.03</p> </li></ul>	Split existing MBS item 31303, creating a new item for rest myocardial perfusion studies (MPS) to remove any financial incentive to perform stress and rest studies over separate days.	4.1
New split 61303B	<p>Item 61303B Single rest myocardial perfusion study</p> <ul style="list-style-type: none"> <li>(a) Performed in conjunction with stress myocardial perfusion imaging (item 61303A) for: <ul style="list-style-type: none"> <li>(i) Evaluation of symptoms possibly related to cardiac ischaemia</li> <li>(ii) Assessment of functional severity of known CAD</li> <li>(iii) Pre-operative assessment of a patient at intermediate or high risk of CAD; or</li> </ul> </li> <li>(b) Performed for evaluation of myocardial perfusion and left ventricular function in patients with suspected cardiomyopathy</li> </ul> <p>Fee: \$329.02</p>	Split existing MBS item 31303, creating a new item for rest MPS studies to remove any financial incentive to perform stress and rest studies over separate days.	4.1
New	Whole body FDG PET/CT for the diagnosis of known or suspected FDG-avid solid tumour.	All existing MBS PET items be consolidated into four items, covering diagnosis, staging, response assessment and recurrence (re-staging) for all fluorodeoxyglucose (FDG)-avid tumours.	4.4
New	Whole body FDG PET/CT for the staging of known or suspected FDG-avid solid tumour.	All existing MBS PET items be consolidated into four items, covering diagnosis, staging, response assessment and recurrence (re-staging) for all	4.4





Item	Descriptor	Recommendation	Section reference
		fluorodeoxyglucose (FDG)-avid tumours.	
New	Whole body FDG PET/CT for response assessment of known or suspected FDG-avid solid tumour.	All existing MBS PET items be consolidated into four items, covering diagnosis, staging, response assessment and recurrence (re-staging) for all fluorodeoxyglucose (FDG)-avid tumours.	4.4
New	Whole body FDG PET/CT for recurrence (re-staging) of known or suspected FDG-avid solid tumour.	All existing MBS PET items be consolidated into four items, covering diagnosis, staging, response assessment and recurrence (re-staging) for all fluorodeoxyglucose (FDG)-avid tumours.	4.4