Therapeutic nuclear medicine therapy for neuroendocrine neoplasms

Last updated: 12 September 2025

- From 1 November 2025 a new item for a type of peptide receptor radionuclide therapy (PRRT), ¹⁷⁷Lutetium-DOTA-somatostatin receptor agonist (Lu-DOTA) treatment, will be listed on the Medicare Benefits Schedule (MBS) for patients with advanced neuroendocrine neoplasm (NEN) with high somatostatin receptor (H-SSTR) expression, including phaeochromocytomas and paragangliomas.
- A new whole-body ⁶⁸Gallium-DOTA-octreotate SSTR (⁶⁸Ga-DOTA) positron emission tomography (PET) item will also be listed to determine a patient's suitability to undergo PRRT treatment, monitor response to PRRT, and assess the progression of recurrent or metastatic disease in patients with known somatostatin receptor positive NEN.
- This change is relevant to health professionals who request, provide and claim Lu-DOTA treatment under the MBS, as well as patients, private health insurers and hospitals.

What are the changes?

Effective 1 November 2025, the following changes will occur:

- One new item (61530) will be listed in the Diagnostic Imaging Services Table for a whole-body ⁶⁸Ga-DOTA PET scan to assess eligibility to undergo PRRT treatment, monitor response to PRRT, and assess the progression of recurrent or metastatic disease in known somatostatin receptor positive NEN.
- One new item (16060) for Lu-DOTA treatment will be listed in the General Medical Services Table to treat eligible patients with advanced NEN with H-SSTR expression.

Private Health Insurance Classifications for the items will be applied as follows:

Diagnostic whole-body ⁶⁸Ga-DOTA PET scan (item 61530)

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

Lu-DOTA treatment (item 16060)

- <u>Clinical category</u>: Chemotherapy, radiotherapy and immunotherapy for cancer, of the <u>Private Health Insurance (Complying Product) Rules 2015</u>
- Procedure type: Unlisted of the <u>Private Health Insurance (Benefit Requirements) Rules</u>
 2011

Why are the changes being made?

These new MBS services will support people with advanced NEN with H-SSTR expression, including phaeochromocytomas and paragangliomas, to access Lu-DOTA treatment to control their symptoms, slow disease progression, and improve quality of life.

The listing of these services was recommended by the Medical Services Advisory Committee (MSAC) in November 2024. In the 2025-2026 Federal Budget the Australian Government announced that the MBS items would be listed from 1 November 2025. Further details about MSAC applications can be found under MSAC Applications on the MSAC website (Medical Services Advisory Committee).

What does this mean for requestors and providers?

Specialists and consultant physicians may request a whole-body ⁶⁸Ga-DOTA PET scan (item 61530) for patients with NEN who meet specific clinical criteria. This service provides critical information to guide clinicians across several stages of disease management, including treatment planning, assessment of suitability for PRRT and monitoring of disease progression or recurrence.

Specialists may provide Lu-DOTA treatment (item 16060), a type of PRRT, for patients with histologically confirmed and inoperable NEN, either locally advanced or metastatic, who have documented disease progression or uncontrolled symptoms related to their NEN despite standard therapy. Patients eligible for this service must be assessed as suitable for therapy by a formally convened NEN multidisciplinary board.

Item 16060 is not limited to a particular type of Lu-DOTA product, and the schedule fee includes all aspects of the treatment cycle: including patient preparation, administration and immediate aftercare, a consultation with the supervising specialist within 36 hours of treatment, and a post-infusion SPECT scan if performed.

Note TN3.3 provides additional information on the requirements for the use of Item 16060.

How will these changes affect patients?

NENs are a rare type of cancer that form in neuroendocrine cells which are found throughout the body, and form part of a network of glands and nerve cells that make hormones and release them into the bloodstream. Some neuroendocrine tumour cells have specific receptors on their surface called somatostatin receptors. If a ⁶⁸Ga-DOTA PET scan finds that the cells have a high number of these receptors the patient may be eligible for Lu-DOTA treatment, which is designed to enter the tumour cell and damage it.

These new MBS services will provide greater access to Lu-DOTA treatment for eligible patients who have advanced NEN with H-SSTR expression to better control the symptoms of disease, slow disease progression, and improve quality of life.

Patients may be required to pay an upfront amount to their service provider to begin Lu-DOTA treatment, and in some cases, this may be a significant amount. Where the upfront payment is \$10,000 or more, a <u>Medicare claim form (MS014)</u> must be completed and submitted to Medicare by mail or in-person at a Services Australia service centre. These claims cannot be submitted online.

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

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

More information about Medicare claims and the EMSN, including the current calendar year EMSN thresholds, can be found on the <u>Services Australia</u> website.

Patients can view and manage their Medicare Safety Net and update their personal and bank account details in their Medicare online account through myGov, or by calling Medicare on 132 011.

Who was consulted on the changes?

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

How will the changes be monitored and reviewed?

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

Where can I find more information?

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

Providers seeking advice on interpretation of MBS items, explanatory notes and associated legislation can use the department's email advice service by emailing askMBS@health.gov.au.

Private health insurance information on the product tier arrangements is available at www.privatehealth.gov.au. Detailed information on the MBS item listing within clinical categories is available on the department's website. Private health insurance minimum accommodation benefits information, including MBS item accommodation classification, is available in the latest version of the Private Health Insurance (Benefit Requirements)

Rules 2011 found on the <u>Federal Register of Legislation</u>. If you have a query in relation to private health insurance, you should email <u>PHI@health.gov.au</u>.

Subscribe to 'News for Health Professionals' on the Services Australia website to receive regular news highlights.

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

The data file for software vendors when available can be accessed via the Downloads page.

New item descriptors (from 1 November 2025)

* The Greatest Permissible Gap (GPG) has been applied to the out-of-hospital benefit (see asterisk below). From 1 November 2025, the GPG is set at \$104.50. This means that all out-of-hospital Medicare services which have a schedule fee of \$683.00 or more will attract a Medicare benefit that is greater than 85% of the MBS fee.

Category 5 - Diagnostic Imaging Services

Group I4 - Nuclear Medicine Imaging

Subgroup 2 - PET

61530

Whole body ⁶⁸Ga-DOTA-somatostatin receptor agonist PET study for:

- a) staging of histologically confirmed neuroendocrine neoplasm (NEN) considered surgically incurable on conventional imaging,
- b) evaluation of somatostatin receptor expression of histologically confirmed and inoperable NEN, either locally advanced or metastatic, under consideration for peptide receptor radionuclide therapy (PRRT),
- c) evaluation of response to PRRT therapy, or
- d) evaluation of suspected recurrent or metastatic disease in known somatostatin receptor positive NEN.

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Fee: \$953.00 Benefit: 85%: \$848.50*, 75%: \$714.75

Private Health Insurance Classification:

- Clinical category: Support List (DI)
- Procedure type: Type C

Category 3 - Therapeutic Procedures

Group T3 – Therapeutic Nuclear Medicine

Subgroup 2 – Theranostics

16060

¹⁷⁷Lutetium-DOTA-somatostatin receptor agonist treatment cycle for patients with histologically confirmed and inoperable neuroendocrine neoplasm (NEN), either locally advanced or metastatic, with documented disease progression or uncontrolled symptoms related to their NEN despite standard therapy who:

- a) have high tumour somatostatin receptor expression demonstrated on whole body ⁶⁸Ga DOTA somatostatin agonist PET study; and
- b) are considered suitable for a course of ¹⁷⁷Lutetium-DOTA-somatostatin receptor agonist therapy by a formally convened NEN multidisciplinary board.

Includes the necessary patient preparation, administration and treatment, immediate patient aftercare required for the treatment cycle, consultation with the supervising specialist within 36 hours of treatment, and a post-infusion SPECT if performed.

Fee: \$9,999.95 Benefit: 85%: \$ 9,895.45*, 75%: \$ 7,499.96

Private Health Insurance Classification:

- Clinical category: Chemotherapy, radiotherapy and immunotherapy for cancer
- Procedure type: Unlisted

Note TN.3.3: Item 16060 – 177Lutetium-DOTA-somatostatin receptor agonist treatment for neuroendocrine neoplasm

177Lutetium-DOTA-somatostatin receptor agonist (Lu-DOTA) treatment is a type of peptide receptor radionuclide therapy which is given in multiple individual cycles over a period of time, with a period of recovery between cycles (typically 6-8 weeks). When a treatment cycle is repeated multiple times on a regular schedule, it is called a course of treatment.

An eligibility requirement for Item 16060 is that patients must be considered suitable for a course of Lu-DOTA treatment by a formally convened NEN multidisciplinary board.

For the purposes of Item 16060, a formally convened neuroendocrine multidisciplinary board is a formal board of relevant practitioners, including specialists in medical oncology and nuclear medicine with experience in managing NEN, endocrinology and surgery specialists, as well as medical practitioners from different areas of medical practice (including general practitioners). Allied health practitioners relevant to NEN treatment may be part of the board. The board must include at least one oncologist and one surgeon.

For Item 16060, the item refers to an individual treatment cycle and is inclusive of the following components of the service:

- a. patient preparation required prior to the administration of the radiopharmaceutical in the treatment cycle (including the administration of the necessary prophylactic amino acid infusions and antiemetics),
- b. the cost, preparation and administration of the radiopharmaceutical,
- c. patient monitoring during the administration of the treatment (including the risk of carcinoid crisis and other severe hormonal flare syndromes) and immediate patient aftercare required for the safe discharge of the patient post-infusion,
- d. a consultation with the supervising theranostic specialist within 36 hours of the time the treatment cycle occurred, to monitor patient progress and confirm individual medication and monitoring requirements with adjustments where necessary, and
- e. post-infusion single photon emission tomography if performed.

Training requirements

Service providers administering this item should have the appropriate training and competency to deliver the service. Attendance of healthcare professionals skilled in the administration of therapeutic radiopharmaceuticals and associated patient care is required for this service. Remote supervision is not appropriate for this item.

The Australasian Association of Nuclear Medicine Specialists has published recommendations for therapeutic nuclear medicine training requirements in the <u>AANMS</u>

<u>Position Statement: Practice of Theranostics in Australia</u> and provides theranostics training courses.

Additionally, the Royal Australian and New Zealand College of Radiologists has developed <u>Competencies for Professional Development in Theranostics</u> for radiologists.

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

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