

MSAC application 1795

Positron Emission Tomography/Computed Tomography (PET/CT) Dopaminergic Imaging for Evaluating Parkinsonism

Application for MBS eligible service or health technology

HPP Application number:

HPP200244

Application title:

PET/CT Dopaminergic Imaging for Evaluating Parkinsonism

Submitting organisation:

AUSTRALASIAN ASSOCIATION OF NUCLEAR MEDICINE SPECIALISTS

Submitting organisation ABN:

71158642267

Application description

Succinct description of the medical condition/s:

Parkinson disease, in some cases, is not easy to diagnose because the signs and symptoms are not always standard and there are other conditions that can mimic the disease.

There are also some patients with a diagnosis of Parkinson disease who do not respond to standard treatment.

Succinct description of the service or health technology:

PET dopaminergic imaging is an accurate way of diagnosing Parkinson disease from non-Parkinson disease in these cases, so that the correct treatments can be used and started earlier, making a difference to the quality of life of those affected.

Application contact details

Are you the applicant, or are you a consultant or lobbyist acting on behalf of the applicant?

Applicant

Are you applying on behalf of an organisation, or as an individual?

Organisation

Applicant organisation name:

Application details

Does the implementation of your service or health technology rely on a new listing on the Pharmaceutical Benefits Scheme (PBS) and/or the Prescribed List?

No

Is the application for a new service or health technology, or an amendment to an existing listed service or health technology?

New

Relevant MBS items

Please select any relevant MBS items.

MBS item number	Selected reason type
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What is the type of service or health technology?

Investigative

Please select the type of investigative health technology: *(if investigative)*

Position emission tomography scans

PICO sets

Application PICO sets:

PICO set 1

Dopaminergic Imaging in cases with a diagnosis of Parkinson Disease, who are not responding as expected from standard therapy

Purpose category:

Diagnosis / sub-classification

Purpose description:

To establish a diagnosis or disease (sub)classification in symptomatic or affected patients

What additional purpose(s) could the health technology be used for, other than the purposes listed above for this PICO set?

Purpose category:

Monitoring

Purpose description:

To monitor a condition over time.

Rationale:

This is not a standard indication at present

Population

Describe the population in which the proposed health technology is intended to be used:

This examination is used to assess patients with a diagnosis of Parkinson Disease (PD) but who have not had a typical response to standard PD therapy. It is estimated that 10% of those with a diagnosis of Parkinson Disease presenting to a movement disorder clinic would be considered suitable for the imaging study.

Select the most applicable Medical condition terminology (SNOMED CT):

138875005

Intervention

Name of the proposed health technology:

Dopaminergic PET/CT

Comparator

Nominate the appropriate comparator(s) for the proposed medical service (i.e. how is the proposed population currently managed in the absence of the proposed medical service being available in the Australian health care system). This includes identifying health care resources that are needed to be delivered at the same time as the comparator service:

No comparator.

Outcomes

Outcome description – please include information about whether a change in patient management, or prognosis, occurs as a result of the test information:

The MAP-DOPA trial indicates 26% of patients referred for dopaminergic PET/CT imaging had a change in diagnosis because of PET investigation; this included changes from PD to non-PD and non-PD to PD. 19% of were cases of a clinical diagnosis of PD, who had a change of diagnosis to non PD and 6% non-PD to PD.

Proposed MBS items

Proposed item:

AAAAA

MBS item number (where used as a template for the proposed item)

Proposed category:

DIAGNOSTIC IMAGING SERVICES

Proposed group:

NUCLEAR MEDICINE IMAGING

Proposed item descriptor:

Dopaminergic imaging of the brain for assessment of Parkinson disease, if:
a. clinical examination of the patient by a specialist, is equivocal; and
b. a service to which this item number applies has not been performed in the previous 12 months.

Proposed MBS fee:

\$950.00

Indicate the overall cost per patient of providing the proposed health technology:

\$0.00

Please specify any anticipated out of pocket expenses:

\$0.00

Provide any further details and explain:

There should be no need for patients to pay any fee

How is the technology / service funded at present? (For example: research funding; State-based funding; self-funded by patients; no funding or payments):

1. State based at RBH (QLD), Austin Hospital (VIC).
2. Self- funded patients.
3. Trials- SAHMRI (SA).

Claims

In terms of health outcomes (comparative benefits and harms), is the proposed technology claimed to be superior, non-inferior or inferior to the comparator(s)?

Superior

Please state what the overall claim is, and provide a rationale:

The accuracy of clinical diagnosis of PD ranges between 73- 80%. Dopaminergic PET can differentiate clearly has between normal (non-PD) or abnormal (PD) appearance with an accuracy rating of 93%. This allows for diagnoses to be established earlier in the clinical management and with a higher level of accuracy.

The MAP-DOPA trial indicates 26% of patients referred had a change in diagnosis as a result of PET investigation; this included changes from PD to non-PD and non-PD to PD.

Estimated utilisation

Estimate the prevalence and/or incidence of the proposed population:

Approximately 19,000 people are diagnosed with Parkinson's Disease each year in Australia, with complex cases typically referred to specialist movement disorder clinics. An estimated 10% of the patient population sent to a movement disorder clinic would benefit significantly from dopaminergic PET investigation

Provide the percentage uptake of the proposed health technology by the proposed population:

Year 1 estimated uptake (%):

30

Year 2 estimated uptake (%):

30

Year 3 estimated uptake (%):

30

Year 4 estimated uptake (%):

70

Estimate the number of patients who will utilise the proposed technology for the first full year:

600

Optionally, provide details:

Based on numbers recruited from all movement disorder clinics in SA during trial.

Will the technology be needed more than once per patient?

No, once only

PICO set 2

Dopaminergic PET imaging for the evaluation of Parkinsonism

Purpose category:

Diagnosis / sub-classification

Purpose description:

To establish a diagnosis or disease (sub)classification in symptomatic or affected patients

What additional purpose(s) could the health technology be used for, other than the purposes listed above for this PICO set?

Purpose category:

Monitoring

Purpose description:

To monitor a condition over time

Rationale:

This test has been used in the trial setting to evaluate drug treatment response, but at this stage is not used in the clinical setting.

Population

Describe the population in which the proposed health technology is intended to be used:

This examination is used to assess patients with parkinsonism for a potential diagnosis of Parkinson Disease (PD). Patients presenting atypically and are subsequently difficult to diagnose clinically and/or have not had a typical response to Parkinson Disease therapy would benefit significantly in order to confirm or exclude a PD diagnosis.

Select the most applicable Medical condition terminology (SNOMED CT):

49049000

Intervention

Name of the proposed health technology:

Dopaminergic PET imaging for the evaluation of Parkinsonism

Comparator

Nominate the appropriate comparator(s) for the proposed medical service (i.e. how is the proposed population currently managed in the absence of the proposed medical service being available in the Australian health care system). This includes identifying health care resources that are needed to be delivered at the same time as the comparator service:

No comparator. 123 I DAT SPECT is not available in Australia.

Outcomes

Outcome description – please include information about whether a change in patient management, or prognosis, occurs as a result of the test information:

Health benefits/harms:

Patients will benefit significantly from receiving an accurate diagnosis earlier in their management. This would consequently allow patients with confirmed Parkinson's Disease to access appropriate medication and allied health support earlier in their clinical pathway, resulting in an overall improved quality of life and long-term health outcomes.

Similarly, patients with an atypical outcome that excludes a diagnosis of Parkinson's Disease would avoid unnecessary prescription of inappropriate medication. This

would significantly minimise unpleasant and avoidable adverse effects following incorrect treatment, as well as reduce all superfluous costs the patient may have incurred.

Value of knowing:

Participants enrolled in the MAP-DOPA trial completed qualitative questionnaires preceding and following their 18F-DOPA PET scans. Participants commonly reported frustration with the lack of clarity in regard to their diagnosis, as well as with the amount of time spent trialling various treatments and interventions to exclude other diagnoses. Additional qualitative feedback from the referring clinicians has highlighted the value of providing access to the scan earlier in the clinical pathway to gain certainty on a patient's subsequent management and minimise futile use of resources and time, as well improving long-term outcomes.

An increase in diagnostic certainty following implementation of the scan was reported by the treating neurologist in 90% of the enrolled cohort. Additionally, the trial identified a change in diagnosis in 26% of patients with Parkinsonian symptoms who have been referred for 18-F-DOPA from movement disorder outpatient specialist clinics. This means that patients who do not have PD are not subjected to trial of medication that is not clinically beneficial, can be potentially detrimental and incur expense. Patients with a scan indicating PD may be started on therapy earlier and have access to relatively invasive therapies, such as deep brain stimulation, earlier, subsequently allowing for improved clinical outcomes and improved quality of life.

Proposed MBS items

Proposed item:

AAAAA

MBS item number (where used as a template for the proposed item):

61560

Proposed category:

DIAGNOSTIC IMAGING SERVICES

Proposed group:

NUCLEAR MEDICINE IMAGING

Proposed item descriptor:

FDG PET study of the brain, performed for the diagnosis of Alzheimer's disease, if: clinical evaluation of the patient by a specialist, or in consultation with a specialist, is equivocal; and the service includes a quantitative comparison of the results of the study with the results of an FDG PET study of a normal brain from a reference database; and a service to which this item applies has not been performed on the patient in the previous 12 months; and a service to which item 61402 applies has not been performed on the patient in the previous 12 months for the diagnosis or management of Alzheimer's disease Applicable not more than 3 times per lifetime(R)

Proposed MBS fee:

\$950.00

Indicate the overall cost per patient of providing the proposed health technology:

\$950.00

Please specify any anticipated out of pocket expenses:

\$0.00

Provide any further details and explain:

The number of tests is limited to 2 per lifetime. The repeat test should not be performed within 12 months.

How is the technology / service funded at present? (For example: research funding; State-based funding; self-funded by patients; no funding or payments):

1. State based at RBH (QLD), Austin Hospital (VIC).
2. Self-funded by patients.
3. Trials-SA, SAHMRI.

Claims

In terms of health outcomes (comparative benefits and harms), is the proposed technology claimed to be superior, non-inferior or inferior to the comparator(s)?

Superior

Please state what the overall claim is, and provide a rationale:

No comparator

Estimated utilisation

Estimate the prevalence and/or incidence of the proposed population:

Approximately 19,000 people are diagnosed with Parkinson's Disease each year in Australia, with complex cases typically referred to specialist movement disorder clinics. An estimated 10% of the patient population sent to a movement disorder clinic would benefit significantly from dopaminergic PET investigation.

This would include patients presenting with Parkinsonian symptoms, but are diagnostically complex, e.g. presenting only with tremor, or with atypical signs, or with progressive neurological decline suggestive of Lewy Body Dementia. The investigation would additionally benefit patients who are undergoing treatment for Parkinson's Disease but are not responding suitably.

Dopaminergic imaging would be ordered by the medical specialist after clinical evaluation fails to elicit a clear diagnosis of Parkinson's disease.

This imaging has a sensitivity of 95%, specificity of 100% , positive predictive value 100% and negative predictive value 88% in those patients presenting to a specialist clinic with symptoms and signs of Parkinson Disease.

Provide the percentage uptake of the proposed health technology by the proposed population:

Year 1 estimated uptake (%):

20

Year 2 estimated uptake (%):

20

Year 3 estimated uptake (%):

50

Year 4 estimated uptake (%):

70

Estimate the number of patients who will utilise the proposed technology for the first full year:

Optionally, provide details:

Expected to be n=1500 across Australia, based on enrolment numbers for the MAP-DOPA trial with n=300 across the 3 movement disorder clinics in South Australia.

Will the technology be needed more than once per patient?

No, once only

Consultation

List all entities that are relevant to the proposed service / health technology. The list can include professional bodies / organisations who provide, request, may be impacted by the service/health technology; sponsor(s) and / or manufacturer(s) who produce similar products; patient and consumer advocacy organisations or individuals relevant to the proposed service/health technology.

Entities who provide the health technology/service

Australasian Association of Nuclear Medicine Specialists

THE ROYAL AUSTRALIAN AND NEW ZEALAND COLLEGE OF RADIOLOGISTS LIMITED

THE ROYAL AUSTRALASIAN COLLEGE OF PHYSICIANS

Entities who request the health technology/service

Movement Disorder Society of Australia and New Zealand

THE ROYAL AUSTRALIAN AND NEW ZEALAND COLLEGE OF PSYCHIATRISTS

THE ROYAL AUSTRALASIAN COLLEGE OF PHYSICIANS

Entities who may be impacted by the health technology/service

AUSTRALASIAN ASSOCIATION OF NUCLEAR MEDICINE SPECIALISTS

THE ROYAL AUSTRALIAN AND NEW ZEALAND COLLEGE OF PSYCHIATRISTS

THE ROYAL AUSTRALASIAN COLLEGE OF PHYSICIANS

THE ROYAL AUSTRALIAN AND NEW ZEALAND COLLEGE OF RADIOLOGISTS LIMITED

Entity relevant to the proposed service/health technology

PARKINSONS SOUTH AUSTRALIA INCORPORATED

PARKINSON'S AUSTRALIA LIMITED

Entity who produces similar products

South Australian Health and Medical Research Institute Limited

Regulatory information

Would the proposed health technology involve the use of a medical device, in-vitro diagnostic test, radioactive tracer or any other type of therapeutic good?

Yes

Has it been listed or registered or included in the Australian Register of Therapeutic Goods (ARTG) by the Therapeutic Goods Administration (TGA)?

No

Is the therapeutic good classified by the TGA as either a Class III or Active Implantable Medical Device (AIMD) against the TGA regulatory scheme for devices?

No

Is the therapeutic good to be used in the service exempt from the regulatory requirements of the Therapeutic Goods Act 1989?

No

Is the therapeutic good classified by the TGA as for Research Use Only (RUO)?

Yes