MSAC application 1822

F-18 Fluorodeoxyglucose (FDG) positron emission tomography (PET) for evaluation of complex infection

Application for MBS eligible service or health technology

HPP Application number:

HPP200417

Application title:

F-18 FDG PET for evaluation of complex infection

Submitting organisation:

Queensland X-Ray Pty Ltd

Submitting organisation ABN:

40094502208

Application description

Succinct description of the medical condition/s:

F-18-FDG PET/CT facilitates early diagnostic certainty, with consistently high diagnostic accuracy (>85%) across multiple infectious diseases and is internationally recommended as a preferred imaging modality in appropriate clinical contexts, if base-line investigations fail to sufficiently provide a diagnosis or are contraindicated. These diseases include:

- Fever of unknown origin and neutropenic fever
- Suspected spinal infections
- Suspected osteomyelitis
- Suspected bone and joint infections in children, where FDG-PET can remove the necessity for general
- Suspected prosthetic joint infection or other orthopaedic hardware infection, if more than 2 years post-surgery
- Suspected infective endocarditis
- Extrapulmonary non-tuberculous mycobacterial (EPNTM) infection
- Bacteraemia where metastatic infection is suspected

Currently used modalities have an evidence base demonstrating they are inferior in accuracy, more costly, and may cause diagnostic delays.

Succinct description of the service or health technology:

The proposed service is 18F-FDG PET scanning for the evaluation and diagnosis of the aforementioned infection syndromes.

PET is a minimally invasive nuclear medicine technique that uses short-lived radiotracers to detect infections by visualising metabolic and molecular processes in vivo. In infection imaging, PET using F-18-FDG identifies sites of activated leukocyte metabolism and altered perfusion (due to the hosts inflammatory response to a pathogen), enabling sensitive detection of both focal and systemic disease. This functional information complements the structural detail provided by CT, allowing improved localisation and characterisation of active infectious pathology.

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?

Individual

Applicant organisation name:

Queensland X-Ray Pty Ltd

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

What is the type of service or health technology?

Investigative

Please select the type of investigative health technology:

Position emission tomography scans

PICO sets

Application PICO sets:

PICO sets	
1	Complex Infection
2	Fever of Unknown origin and Neutropenic Fever

PICO set 1: Complex Infection

State the purpose(s) of the health technology for this PICO set and provide a rationale:

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:
Outcome / response assessment

Purpose description:
To assess an outcome or response following an intervention or treatment

Rationale:
FDG PET should be used for initial diagnosis after baseline investigations do not provide a diagnosis. After treatment has commenced, the baseline investigations should provide evidence of response.

Population

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

FDG-PET for complex infection is intended primarily for patients in whom standard initial clinical evaluation (which may include conventional imaging) have not provided a definitive diagnosis of infection, are contraindicated, or where the infection is difficult to localize or characterize which includes:

- Suspected spinal infections (vertebral osteomyelitis, discitis or epidural abscess)
- Suspected osteomyelitis in cases of a known soft tissue infection (including diabetic foot ulcers), fracture related osteomyelitis, and to assess for dissemination of infection to other skeletal sites or organs
- Suspected bone and joint infections in children, where FDG-PET can remove the necessity for general anaesthesia (as required for MRI) and enable better ability to distinguish between acute and chronic infections, or reparative bone tissue;
- Suspected prosthetic joint infection or other orthopaedic hardware infection, if more than 2 years post-surgery
- Suspected infective endocarditis, including following congenital heart disease, or due to prosthetic valve infection, cardiac implantable electronic device infection and septic emboli
- Extrapulmonary non-tuberculous mycobacterial (EPNTM) infection
- Bacteraemia (for example Staphylococcus aureus or other pathogens with a high risk of metastatic infection) where metastatic infection is suspected

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

Intervention

Name of the proposed health technology:
F-18 FDG PET

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:

The application proposes the following existing items could be relevant comparators:

Radiography:
56223 - Computed tomography—scan of spine, lumbosacral region, without intravenous contrast medium
56807 - Computed tomography—scan of chest, abdomen and pelvis with or without scans of soft tissues of neck with intravenous contrast medium and with any scans of chest, abdomen and pelvis with or without scans of soft tissue of neck before intravenous contrast injection, when performed
56007 - Computed tomography—scan of brain with intravenous contrast medium and with any scans of the brain before intravenous contrast injection, when performed
56030 - Computed tomography—scan of facial bones, para nasal sinuses or both, with scan of brain, without intravenous contrast medium
57712, 56620, 56622, 55867 - Computed Tomography - imaging of hip, knee, lower extremity, shoulder/upper arm without contrast
63304 - MRI—scan of musculoskeletal system for infection arising in bone or musculoskeletal system

Nuclear Medicine
61429 – Whole-body Ga 67 study (planar)
61430 – Whole-body Ga 67 study with SPECT
61442 - Whole-body Ga 67 study with SPECT (two or more body regions separately)
61450 - Localised study using gallium
61453 - Localised study using gallium, with SPECT
61477 - Supplementary item for Ga 67 scans
61462 - Repeat planar and SPECT imaging, or repeat planar imaging or single photon emission tomography imaging on an occasion subsequent to the performance of item , 61429, 61430, 61442, 61450, 61453, if there is no additional administration of radiopharmaceutical and if the previous radionuclide scan was abnormal or equivocal

61433 – Whole-body study using cells labelled with technetium
61434 - Whole-body labelled-cell study + SPECT
61454 - Localised study using cells labelled with technetium
61457 - Localised study using cells labelled with technetium, with SPECT
61446 - Regional scintigraphic study, using an approved bone scanning agent, including when undertaken, blood flow imaging, blood pool imaging and repeat imaging on a separate occasion
61449 - Regional scintigraphic study, using an approved bone scanning agent and SPECT, including when undertaken, blood flow imaging, blood pool imaging and repeat imaging on a separate occasion

Outcomes

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

A change in prognosis may occur through earlier diagnosis and timely initiation of appropriate therapy, more complete source control in deep-seated or disseminated infection, reduction in relapse risk through confirmation of treatment response, and prevention of morbidity associated with delayed diagnosis. FDG PET/CT is particularly beneficial in scenarios where MRI or CT are limited by metal artefact (such as prosthetic joints or vascular grafts), post-operative or post-treatment structural changes that obscure active infection, or the inability of conventional imaging to provide whole-body assessment for disseminated disease.

Proposed MBS items

Proposed item: AAAAA

Category number:
5

Category description:
Diagnostic Imaging Services

Proposed item descriptor:
Positron emission tomography study using 18F-fluorodeoxyglucose for the evaluation of suspected deep-seated or complex infection in whom first-line investigations were equivocal, including one or more of:
i. Suspected spinal infection (vertebral osteomyelitis, discitis or epidural abscess); or
ii. Suspected osteomyelitis in cases of a known soft tissue infection (including diabetic foot ulcers), fracture related osteomyelitis, and to assess for dissemination of

infection to other skeletal sites or organs
iii. Suspected prosthetic joint infection or other orthopaedic hardware infection, if more than 2 years post surgery
iv. Suspected bone and joint infections in children, where FDG-PET can remove the necessity for general anaesthesia (as required for MRI) and enable better ability to distinguish between acute and chronic infections, or reparative bone tissue;
v. Suspected infective endocarditis, including following congenital heart disease, or due to prosthetic valve infection, cardiac implantable electronic device infection and septic emboli
vi. High-risk bacteraemia (for example Staphylococcus aureus or other pathogens with a high risk of metastatic infection) where metastatic infection is suspected
vii. Extrapulmonary non-tuberculous mycobacterial (EPNTM) infection with suspected disseminated infection

Proposed MBS fee:
$953.00

Indicate the overall cost per patient of providing the proposed health technology:
$953.00

Please specify any anticipated out of pocket expenses:
$0.00

Provide any further details and explain:
Price matched to medicare rebate for other FDG PET scans

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

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 clinical claim is that 18F-FDG PET imaging is superior to other second-line advanced imaging techniques for patients with complex infection, resulting in a quicker, more accurate diagnosis, and lowered healthcare burden. This can be broken into radiographical techniques and nuclear imaging techniques.

Radiography Techniques

FDG PET/CT provides standardised whole-body imaging and can be performed as a hybrid study with CT or MRI, integrating functional and anatomical information in a single examination. In the early stages of infectious disease, anatomical imaging alone is frequently limited, as structural changes may only become apparent once significant tissue involvement has occurred, leading to lower sensitivity than FDG PET scan. Reliance on lower-sensitivity anatomical imaging is unlikely to alter clinical management and may instead contribute to diagnostic delay, cumulative radiation exposure, and prolonged inpatient hospitalisation.

Nuclear Imaging Techniques

FDG PET/CT demonstrates diagnostic sensitivity comparable to labelled white blood cell scanning and gallium scintigraphy, with all modalities providing whole-body functional imaging for the detection of infection. Compared with Gallium-67 studies, FDG PET/CT offers important practical advantages, including greater tracer availability, lower overall cost, reduced need for close contact restrictions, shorter interruption to breastfeeding, and substantially faster acquisition. In contrast to labelled white blood cell imaging, PET/CT avoids blood handling, enabling safer and more efficient delivery, and tracer availability is less volatile. Image quality is superior, and increasing scanner availability further supports its role as the preferred functional imaging modality in this setting.

Estimated utilisation

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

Spinal infection has an estimated incidence of 2–7 cases per 100,000 people annually in Australia (Phan, 2026), corresponding to approximately 520–1,820 cases per year. If a high estimate of 1% of patients are contraindicated for MRI (Dewey, 2007) and 3% have equivocal MRI findings (Baxi, 2012), an estimated 20–100 patients annually in Australia may require an FDG PET scan.

Osteomelitis has an estimated incidence of 10-100 cases per 100,0008, with the US reporting 21.8 cases per 100,000 population (Bejon, 2017). Australian studies have shown up to 82 cases per 100,000 in Indigenous population (Brischetto, 2016). Taking a conservative estimate of 20 cases per 100,000 population this corresponds to approximately 5,000 new cases of OM per year. Assuming after first-line investigations, approximately 25% of patients have equivocal findings (Kremers, 2015), an estimated 1250 to 2000 patients annually may require an FDG PET scan.

Australian registry and research data show that overall infection incidence after hip and knee replacement is roughly 2,200–2,900 cases annually (Huotari, 2015). While much of this burden occurs within the first two years, international registry studies suggest late PJI incidence stabilises at about 0.07% per prosthesis year after two years (Huotari, 2015). As approximately 1 million Australians have prosthetic joints (Sinagra, 2022), and if around 25% of cases remain equivocal after first-line investigations, approximately 150-200 patients per year would require advanced imaging.

Cardiac Infection studies show an annual incidence of approximately 3–10 cases per 100,000 people per year in developed settings, with regional Australian data reporting about 4.7 per 100,000 in NSW and 3.0 per 100,000 in Victoria (Baskerville, 2012), equating to roughly 2,600 new cases of infective endocarditis per year nationally. Studies have shown that the modified Duke criteria will fail to identify 30-40% of cases (Papadimitriou-Olivgeris, 2025), meaning around 1000 patients will not be diagnosed from first-line investigations.

Bacteraemia and its metastatic prevalence (using available studies on Staphylococcus aureus bacteraemia) is shown to be about 10-20 cases per 100,000 population per year (ASID, n.d), equivalent to roughly 5000 episodes annually. Metastatic complications occur in 15-20% of patients with bacteraemia (Horino, 2015; Bae, 2025), giving an approximation of 1,000–1,500 Australians per year that may be at high risk of metastatic infection.

Extrapulmonary Non-tuberculous mycobacterial (EPNTM) infections are uncommon. However, its true incidence is challenging to quantify given that it is a notifiable condition only in Queensland. In Queensland, between the years 2001 and 2016 a total of 12,219 cases of NTM were reported with an estimated incidence rate increase from 11.10 (95% CI 8.10–15.22) in 2001 to 25.88 (95%CI 21.78–30.73) per 100,000 in 2016 (Thomson, 2020). Further data from Northern Territory found 226 NTM cases between 1989 –2021 demonstrating significant geographic variability in incidence of NTM infection (Nohrenberg, 2023). Extrapulmonary disease represents approximately 20-30% of NTM infections (Goldsmith, 2024), corresponding to approximately 1300–2000 EPNTM cases per year in Australia.

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

Year 1 estimated uptake (%):
10

Year 2 estimated uptake (%):
20

Year 3 estimated uptake (%):
30

Year 4 estimated uptake (%):
40

Estimate the number of patients who will utilise the proposed technology for the first full year:
650

Optionally, provide details:
For patients with Complex Infection, estimates for uptake will assume that PET will eventually replace the metabolic imaging comparator. This will be approximately 50% of the proposed population.

Will the technology be needed more than once per patient?
No, once only

PICO set 2: Fever of Unknown origin and Neutropenic Fever

State the purpose(s) of the health technology for this PICO set and provide a rationale:

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:
Outcome / response assessment

Purpose description:
To assess an outcome or response following an intervention or treatment

Rationale:
FDG PET should be used for initial diagnosis after baseline investigations do not provide a diagnosis. After treatment has commenced, the baseline investigations should provide evidence of response.

Population

Describe the population in which the proposed health technology is intended to be used:
The proposal is for FDG-PET for use in patients with persistent fever in whom a diagnosis of the source cannot be found, or who have persistent or recurrent neutropenic fever, with absence of diagnosis or resolution despite established baseline investigations.

FUO/PUO is defined as:
1. Documented fever ≥38.3 °C on at least two occasions; and
2. Duration of fever ≥3 weeks

Persistent or recurrent high-risk neutropenic fever is defined as
1. Persistent fever: Absolute neutrophil count < 0.5 X 109/L and documented fever ≥38.0°C daily for at least 3 days

OR

2. Recurrent fever: Documented fever ≥38.0 °C which has recurred during same neutropenic episode after an initial episode of neutropenic fever (temperature ≥38.0°C sustained over 1 hour during absolute neutrophil count < 0.5 X 109/L)

Select the most applicable Medical condition terminology (SNOMED CT):
Pyrexia of unknown origin

Intervention

Name of the proposed health technology:
F-18 FDG PET

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:

56807 - Computed tomography—scan of chest, abdomen and pelvis with or without scans of soft tissues of neck with intravenous contrast medium and with any scans of chest, abdomen and pelvis with or without scans of soft tissue of neck before intravenous contrast injection, when performed
56007 - Computed tomography—scan of brain with intravenous contrast medium and with any scans of the brain before intravenous contrast injection, when performed
56030 - Computed tomography—scan of facial bones, para nasal sinuses or both, with scan of brain, without intravenous contrast medium
61429 – Whole-body Ga 67 study (planar)
61430 – Whole-body Ga 67 study with SPECT
61442 - Whole-body Ga 67 study with SPECT (two or more body regions separately)
61477 - Supplementary item for Ga 67 scans
61462 - Repeat planar and SPECT imaging, or repeat planar imaging or single photon emission tomography imaging on an occasion subsequent to the performance of item , 61429, 61430, 61442, 61450, 61453, if there is no additional administration of radiopharmaceutical and if the previous radionuclide scan was abnormal or equivocal

61433 – Whole-body study using cells labelled with technetium
61434 - Whole-body labelled-cell study + SPECT

Outcomes

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

FDG PET/CT has been shown to frequently alter clinical management in patients with fever of unknown origin and neutropenic fever. In FUO, prospective and retrospective studies have demonstrated that FDG PET contributes diagnostically in a substantial proportion of cases and leads to management changes in approximately one-third to one-half of patients. Similarly, studies in neutropenic fever populations report that FDG PET/CT can identify occult infectious foci and influence antimicrobial strategy or duration of therapy.
FDG PET/CT prognostic effect is generally indirect through earlier diagnosis, more accurate localization of disease, and facilitation of targeted therapy. FDG PET has high diagnostic yield and clinical utility, and outcome benefits are mediated by subsequent management decisions.

Proposed MBS items

Proposed item: AAAAA

Category number:
5

Category description:
Diagnostic Imaging Services

Proposed item descriptor:
FUO/PUO is defined as:
- Documented fever ≥38.3 °C on at least two occasions; and
- Duration of fever ≥3 weeks

Persistent or recurrent high-risk neutropenic fever, defined as
- Persistent fever: Absolute neutrophil count < 0.5 X 109/L and documented fever ≥38.0 °C daily for at least 3 days; OR
- Recurrent fever: Documented fever ≥38.0 °C which has recurred during same neutropenic episode after an initial episode of neutropenic fever (temperature ≥38.0 °C sustained over 1 hour during absolute neutrophil count < 0.5 X 109/L)

Proposed MBS fee:
$953.00

Indicate the overall cost per patient of providing the proposed health technology:
$953.00

Please specify any anticipated out of pocket expenses:
$0.00

Provide any further details and explain:
Price matched to medicare rebate for other FDG PET scans

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

Self-funded

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 clinical claim is that 18F-FDG PET imaging is superior to other second-line advanced imaging techniques for patients with FUO and persistent/recurrent neutropenic fever, resulting in a quicker, more accurate diagnosis, and lowered healthcare burden. This can be broken into radiographical techniques and nuclear imaging techniques.

Radiography Techniques

FDG PET/CT provides standardised whole-body imaging and can be performed as a hybrid study with CT or MRI, integrating functional and anatomical information in a single examination. In the early stages of infectious disease, anatomical imaging alone is frequently limited, as structural changes may only become apparent once significant tissue involvement has occurred, leading to lower sensitivity than FDG PET scan. Reliance on lower-sensitivity anatomical imaging is unlikely to alter clinical management and may instead contribute to diagnostic delay, cumulative radiation exposure, and prolonged inpatient hospitalisation.

Nuclear Imaging Techniques

FDG PET/CT demonstrates diagnostic sensitivity comparable to labelled white blood cell scanning and gallium scintigraphy, with all modalities providing whole-body functional imaging for the detection of infection. Compared with Gallium-67 studies, FDG PET/CT offers important practical advantages, including greater tracer availability, lower overall cost, reduced need for close contact restrictions, shorter interruption to breastfeeding, and substantially faster acquisition. In contrast to labelled white blood cell imaging, PET/CT avoids blood handling, enabling safer and more efficient delivery, and tracer availability is less volatile. Image quality is superior, and increasing scanner availability further supports its role as the preferred functional imaging modality in this setting.

Estimated utilisation

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

Based on Australian data, undifferentiated fever can account for approximately 27,300 emergency department presentations per year (0.3% of adult and 1.5% of paediatric ED visits (Ingarfield, 2007)). When using the classic definition of FUO, this reduces to 0.1–0.5% of presentations (Nicolotti, 2013). Evidence from a Northern Queensland cohort indicates that 56.8% of FUO cases remain undiagnosed after first-line investigations, including history, physical examination, complete blood count, serum biochemistry, urinalysis, blood cultures, and chest X-ray (Susilawati, 2016). Applying this proportion suggests that around 5000 patients annually in Australia are left without a diagnosis after initial evaluation.

For Neutropenic fever, based on the PIPPIN study, a conservatively high estimate of persistent/recurrent neutropenic fever is 65% (180/276 consented patients)(Douglas, 2022). Being conservative with estimates of Australians with acute leukaemia and alloHCT (treating as additive, as well as assuming all AML proceed with intensive chemotherapy, which is not the case), we would estimate that FDG-PET/CT would be required for 65% X 11.4 per 100000 population, or 7 per 100000 population, approximating 1800 per year.

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

Year 1 estimated uptake (%):
30

Year 2 estimated uptake (%):
40

Year 3 estimated uptake (%):
50

Year 4 estimated uptake (%):
60

Estimate the number of patients who will utilise the proposed technology for the first full year:
2000

Optionally, provide details:
Many clinicians will still refer for CT first due to availability, as PET is not available in every hospital and is not as highly available. Approximately 15% of the population are in areas with no PET service, and CT is diagnostically useful in approximately 30% of cases of FUO (Kaya, 2025). It can be conservatively estimated that approximately one-third to one-half of the proposed population will utilise PET initially for FUO. For Neutropenic fever, it can be estimated that most of the proposed population will utilise PET, as they are likely to be inpatients at large hospitals that have PET available.

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.

Entity who provides the health technology/service

AUSTRALASIAN ASSOCIATION OF NUCLEAR MEDICINE SPECIALISTS

Entities who request the health technology/service:

AUSTRALASIAN SOCIETY FOR INFECTIOUS DISEASES LIMITED

HAEMATOLOGY SOCIETY OF AUSTRALIA AND NEW ZEALAND

INTERNAL MEDICINE SOCIETY OF AUSTRALIA AND NEW ZEALAND

THE ROYAL AUSTRALASIAN COLLEGE OF PHYSICIANS

Entity who may be impacted by the health technology/service:

AUSTRALASIAN ASSOCIATION OF NUCLEAR MEDICINE SPECIALISTS

THE ROYAL AUSTRALIAN AND NEW ZEALAND COLLEGE OF RADIOLOGISTS LIMITED

Patient and consumer advocacy organisations relevant to the proposed service/health technology:

SPINE SOCIETY OF AUSTRALIA LIMITED

THE CARDIAC SOCIETY OF AUSTRALIA AND NEW ZEALAND

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)? *(*

Yes

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

Please enter all relevant ARTG IDs:

ARTG ID	ARTG name
54251	AUSTIN HEALTH FDG injection BP

Is the intended purpose in this application the same as the intended purpose of the ARTG listing(s)?

Yes

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

No