s22

From: s22
Sent: Tuesday, 23 July 2024 12:12 PM
To: s22
Cc:
Subject: RE: For clearance - MBS costing request for Lutetium for prostate cancer (1686.1) [SEC=~~PROTECTED~~]

If you are happy – it is good to go.

s22

From: s22
Sent: Tuesday, 23 July 2024 11:51 AM
To: s22
Cc: s22
Subject: RE: For clearance - MBS costing request for Lutetium for prostate cancer (1686.1) [SEC=PROTECTED]

Thanks s22 that's appreciated and makes sense to me. I've changed the table to the individual ones below. Can we send this version to HERD?

Thanks,
s22

From: s22 .Health.gov.au>
Sent: Tuesday, 23 July 2024 10:55 AM
To: s22 .Health.gov.au>
Cc: s22 .Health.gov.au>
Subject: RE: For clearance - MBS costing request for Lutetium for prostate cancer (1686.1) [SEC=PROTECTED]

s22

I do not think that you need the assumptions for how you got to the number of services for HERD purposes. Other than to say source is MSAC consideration. I have made some assumptions about BBR and In Hospital proportion.

New Item 61528 (DIST – I4 SG-2)

s47C, s47D

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

s47C, s47D

[redacted]

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

s22
Director, Diagnostic Imaging Section

Diagnostic Imaging and Pathology Branch | Medicare Benefits and Digital Health Division | Health Resourcing Group
Australian Government Department of Health and Aged Care
T: 02.6289.s22 E: s22 s22 health.gov.au |

PO Box 9848, Canberra ACT 2601, Australia

The Department of Health and Aged Care acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

From: s22 s22 Health.gov.au>
Sent: Monday, 22 July 2024 4:23 PM
To: s22 s22 Health.gov.au>
Cc: s22 s22 Health.gov.au>
Subject: For clearance - MBS costing request for Lutetium for prostate cancer (1686.1) [SEC=~~PROTECTED~~]

Hi s22

Please see attached draft MBS costing form for 1686.1 for your consideration and clearance.

s47C

[redacted]

s47C

Thanks,
s22

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Australian Government
Department of Health and Ageing

Medicare Financing & Analysis Branch

MBS Costing Request Form

General Instructions

Please complete each question that is applicable and provide relevant detail. Relevant reports, summaries, tables etc. can be sent as attachments. Send completed requests to 'MBS Costings' inbox. A staff member will contact you after reviewing the information provided and arrange meetings and discussions as required.

If you have any questions, need clarification before completing the request form, please contact s22 s22 and arrange a meeting.

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Information Automatically Included as Part of the Costing

- Bulk Billing Incentives where applicable
- Flow-ons for the Medicare Safety Net and Extended Medicare Safety Net
- In and out of hospital percentages for existing MBS items
- Forecasts of service volumes for existing MBS items
- Indexation applied across forward estimate period, if applicable

MBS Data Request related to the Costing

A request for MBS data or analysis related to the costing can be completed under '***Part F: MBS Data and Analysis Request (if required)'*** of the costing request form. Submitting your data requests with your costing request will streamline the process and ensure completion deadlines are met.

Note that the section can prepare reports from ***CasemixWiz*** (hospital data) if required. Refer to ***Part F***.

Have you already prepared a Summary of key issues related to your Costing Request?

- Please complete ***Part A***. Complete ***Part F*** if required.
- Attach your summary and other related documents
- Please ensure you have covered ***all*** the issues listed in the ***MBS Costing Request Form***
- Suggest you use the same sub headings in your summary as listed in the ***Request Form***
- ***If your summary only addresses a subset of relevant issues, complete the Request Form and refer to your summary as required***

Part A: General Information

Contact Officer Details

A realistic completion date is dependent on the complexities of the costing and availability of relevant information. The costing area will advise of any unanticipated delays.

Name	s22 (M-Wed, Friday) (M-Tues, Thurs-F).
Phone	s22 (02) 5132 s22 s22 (02) 5132 s22
Section	Diagnostic Imaging
Branch	Diagnostic Imaging and Pathology
Division	MBDHD
Date of Request	
Date completed costing needs to be with program area	
If less than 1 week, provide reason for urgency and AS approval	

Part B: General Costing Information

Costing relates to what part(s) of the MBS?

Tick all boxes that apply. ***Double-click box to fill.***

- ☐ GP Consultation
- ☐ Specialist Consultation
- ☒ Diagnostic Imaging
- ☐ Pathology
- ☐ Surgical procedure
- ☒ Non-surgical procedure
- ☐ Diagnostic services
- ☐ Allied Health — Type:
- ☐ Dental — Type:
- ☐ Other — Type:

Title of Policy Proposal

Title: ^{177}Lutetium PSMA treatment for metastatic castrate resistant prostate cancer, including diagnostic whole body PSMA PET scan to determine eligibility for treatment.

Brief description of the policy proposal

Policy summary (1-2) paragraphs) which underpins the proposal. Include relevant background information.

s47C, s47E(d)

Start date for policy proposal (i.e. 1 Nov 2011)

Start date is critical to correctly estimating the impact on the first year of the costing.

Start date: 1 July 2025

Specify Forward Estimate period

Standard forward estimate period is 4 years

Double-click box to fill.

☒ 4 years (standard)

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

☐ Other Please specify

Is the costing based on recommendations of MSAC, PBAC or other organisation?

If 'Other', please provide name of organisation (i.e. PSTC).

Please provide electronic copy of report (Word not PDF)

*Please provide summary of key issues related to development of costing, including page and paragraph reference to the report or other documents, analysis. See cover sheet regarding **Summary of key issues**.*

Double-click box to fill.

☒ MSAC Report Number: Application 1686.1
☐ PBAC Report Number:
☐ Other

Explanation if Other:

MSAC/PBAC Report(s) attached? No

Summary attached? Yes. Please see attached Public Summary Document for 1686.1.

Other attachments provided? Please specify.

Part C: Detailed Costing Information

Current MBS Items

List items to be replaced or modified

If modifying the schedule fee or modifying descriptor, provide assumptions around potential impact on claiming patterns (i.e. increase or decrease the number of services provided)

Provide new schedule fee if applicable

Current Items (provide list of items only):
N/a

Proposed New MBS Items

List new items, including proposed schedule fee

Provide any information, assumptions around the uptake of the new items. For example, can the uptake be modelled based on an existing MBS item?

Are the new items a substitute for an existing item? If yes, provide any available information or assumptions around the percentage substitution.

Are the new items a replacement of current items? Please provide relevant detail.

s47C, s47E(d)

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

s47C, s47E(d)

s47C, s47E(d)

s47C, s47E(d)

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

** Item numbers are indicative, subject to final approval*
*** Greatest permissible gap ($98.70 from 1 November 2023) applied to out of hospital services.*

MBS Flow ons

(excluding flow ons to Bulk Billing Incentives, Medicare Safety Net and Extended Medicare Safety Net (EMSN) – see cover sheet for details)

Will changes have an impact on the utilisation of other MBS items? Provide information, assumptions
For example, new procedural item may require a pathology test or anaesthesia
Tick all boxes that apply. ***Double-click box to fill.***

- ☐ GP Consultation
- ☐ Pathology
- ☐ Diagnostic services
- ☐ Allied Health
- ☐ Specialist Consultation
- ☐ Surgical procedure
- ☒ Diagnostic Imaging
- ☐ Non-surgical procedure

Type:

☐ Dental Type:
☐ Other Type:

Item 61505 (CT for anatomic localisation or attenuation correction). No change to item however this item will be co-claimed with the new whole body PSMA PET item.

MBS Off sets

Are the new items a substitute for an existing item? If yes, provide any available information or assumptions around the percentage substitution.

Are the new items a replacement of current items? Please provide relevant detail.

For example, will the introduction of a longer consultation item for GPs impact on the number of patients seen

Tick all boxes that apply. ***Double-click box to fill.***

☐ GP Consultation ☐ Specialist Consultation ☐ Diagnostic Imaging
☐ Pathology ☐ Surgical procedure ☐ Non-surgical procedure
☐ Diagnostic services
☐ Allied Health Type:
☐ Dental Type:
☐ Other Type:

There are no anticipated offsets identified with these new items.

Part D: Costing Assumptions

Assumptions

Provide as much relevant detail as possible

Indicate if you require a number of scenarios, for example freezing the schedule fee for some items and indexing schedule fee for other items or increasing or decreasing schedule fee for some items

s47C, s47E(d)

[redacted]

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

s47C, s47E(d)

Table 1: Service utilisation: whole body PSMA PET of Item 61258

	Stage of treatment and percentage of patients continuing to next cycle	Year 1	Year 2	Year 3	Year 4	Year 5
Diagnostic testing to determine eligibility for Lutetium treatment	s47E(d), s47C					

Table 2: Service utilisation: initial and continuing Lutetium treatment for mCRPC (Items 16019 and 16020)

	Stage of treatment and percentage of patients continuing to next cycle	Year 1	Year 2	Year 3	Year 4	Year 5
Initial Lutetium treatment phase: Item 16019 (claimable up to two times)	s47E(d), s47C					
Continuing Lutetium treatment phase: Item 16020 (claimable up to four times)						
Total number of Lutetium cycles per year		s47E(d), s47C				

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Part E: Potential flow-on impact on PBS, DVA, MA or other program or portfolio

Pharmaceutical Benefits Scheme (PBS) *Contact program area to discuss.*	
Department of Veteran Affairs (DVA) *Liaisons with external agencies are formally conducted through MBD BMU*	
Medicare Australia (MA) *Program area to prepare an External Costing Request (ERC). Liaison with MA is formally conducted through MBD BMU*	
Other program or portfolio *Contact MBD BMU to discuss*	.

Part F: MBS Data and Analysis Request (if required)

Description of Request

(a) Any restrictions on data (only GPs, item numbers)

(b) Time period (financial year time series starting 2004-05, quarterly)

(c) Data required – services, benefits, number of GPs or patients

(d) Attach example of output tables if available

Note: If required, staff can generate reports from CasemixWiz (i.e. by DRG, public/private hospital splits). Please indicate your requirements below.

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Australian Government
Department of Health and Ageing

Medicare Financing & Analysis Branch

MBS Costing Request Form

General Instructions

Please complete each question that is applicable and provide relevant detail. Relevant reports, summaries, tables etc. can be sent as attachments. Send completed requests to 'MBS Costings' inbox. A staff member will contact you after reviewing the information provided and arrange meetings and discussions as required.

If you have any questions, need clarification before completing the request form, please contact Angela Mikalauskas (x3623) and arrange a meeting.

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Information Automatically Included as Part of the Costing

- Bulk Billing Incentives where applicable
- Flow-ons for the Medicare Safety Net and Extended Medicare Safety Net
- In and out of hospital percentages for existing MBS items
- Forecasts of service volumes for existing MBS items
- Indexation applied across forward estimate period, if applicable

MBS Data Request related to the Costing

A request for MBS data or analysis related to the costing can be completed under '***Part F: MBS Data and Analysis Request (if required)'*** of the costing request form. Submitting your data requests with your costing request will streamline the process and ensure completion deadlines are met.

Note that the section can prepare reports from ***CasemixWiz*** (hospital data) if required. Refer to ***Part F***.

Have you already prepared a Summary of key issues related to your Costing Request?

- Please complete ***Part A***. Complete ***Part F*** if required.
- Attach your summary and other related documents
- Please ensure you have covered ***all*** the issues listed in the ***MBS Costing Request Form***
- Suggest you use the same sub headings in your summary as listed in the ***Request Form***
- ***If your summary only addresses a subset of relevant issues, complete the Request Form and refer to your summary as required***

Part A: General Information

Contact Officer Details

A realistic completion date is dependent on the complexities of the costing and availability of relevant information. The costing area will advise of any unanticipated delays.

Name	s22 (M-Wed, Friday) s22 (M-Tues, Thurs-F).
Phone	Kate: (02) 5132 s22 s22 (02) 5132 s22
Section	Diagnostic Imaging
Branch	Diagnostic Imaging and Pathology
Division	MBDHD
Date of Request	
Date completed costing needs to be with program area	
If less than 1 week, provide reason for urgency and AS approval	

Part B: General Costing Information

Costing relates to what part(s) of the MBS?

Tick all boxes that apply. ***Double-click box to fill.***

- ☐ GP Consultation
- ☐ Pathology
- ☐ Diagnostic services
- ☐ Allied Health Type:
- ☐ Dental Type:
- ☐ Other Type:
- ☐ Specialist Consultation
- ☐ Surgical procedure
- ☒ Diagnostic Imaging
- ☒ Non-surgical procedure

Title of Policy Proposal

Title: ^{177}Lutetium PSMA treatment for metastatic castrate resistant prostate cancer, including diagnostic whole body PSMA PET scan to determine eligibility for treatment.

Brief description of the policy proposal

Policy summary (1-2) paragraphs) which underpins the proposal. Include relevant background information.

s47E(d), s47C

Start date for policy proposal (i.e. 1 Nov 2011)

Start date is critical to correctly estimating the impact on the first year of the costing.

Start date: 1 July 2025

Specify Forward Estimate period

Standard forward estimate period is 4 years

Double-click box to fill.

☒ 4 years (standard)

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

☐ Other Please specify

Is the costing based on recommendations of MSAC, PBAC or other organisation?

If 'Other', please provide name of organisation (i.e. PSTC).

Please provide electronic copy of report (Word not PDF)

*Please provide summary of key issues related to development of costing, including page and paragraph reference to the report or other documents, analysis. See cover sheet regarding **Summary of key issues**.*

Double-click box to fill.

☒ MSAC Report Number: Application 1686.1
☐ PBAC Report Number:
☐ Other

Explanation if Other:

MSAC/PBAC Report(s) attached? No

Summary attached? Yes. Please see attached Public Summary Document for 1686.1.

Other attachments provided? Please specify.

Part C: Detailed Costing Information

Current MBS Items

List items to be replaced or modified

If modifying the schedule fee or modifying descriptor, provide assumptions around potential impact on claiming patterns (i.e. increase or decrease the number of services provided)

Provide new schedule fee if applicable

Current Items (provide list of items only):
N/a

Proposed New MBS Items

List new items, including proposed schedule fee

Provide any information, assumptions around the uptake of the new items. For example, can the uptake be modelled based on an existing MBS item?

Are the new items a substitute for an existing item? If yes, provide any available information or assumptions around the percentage substitution.

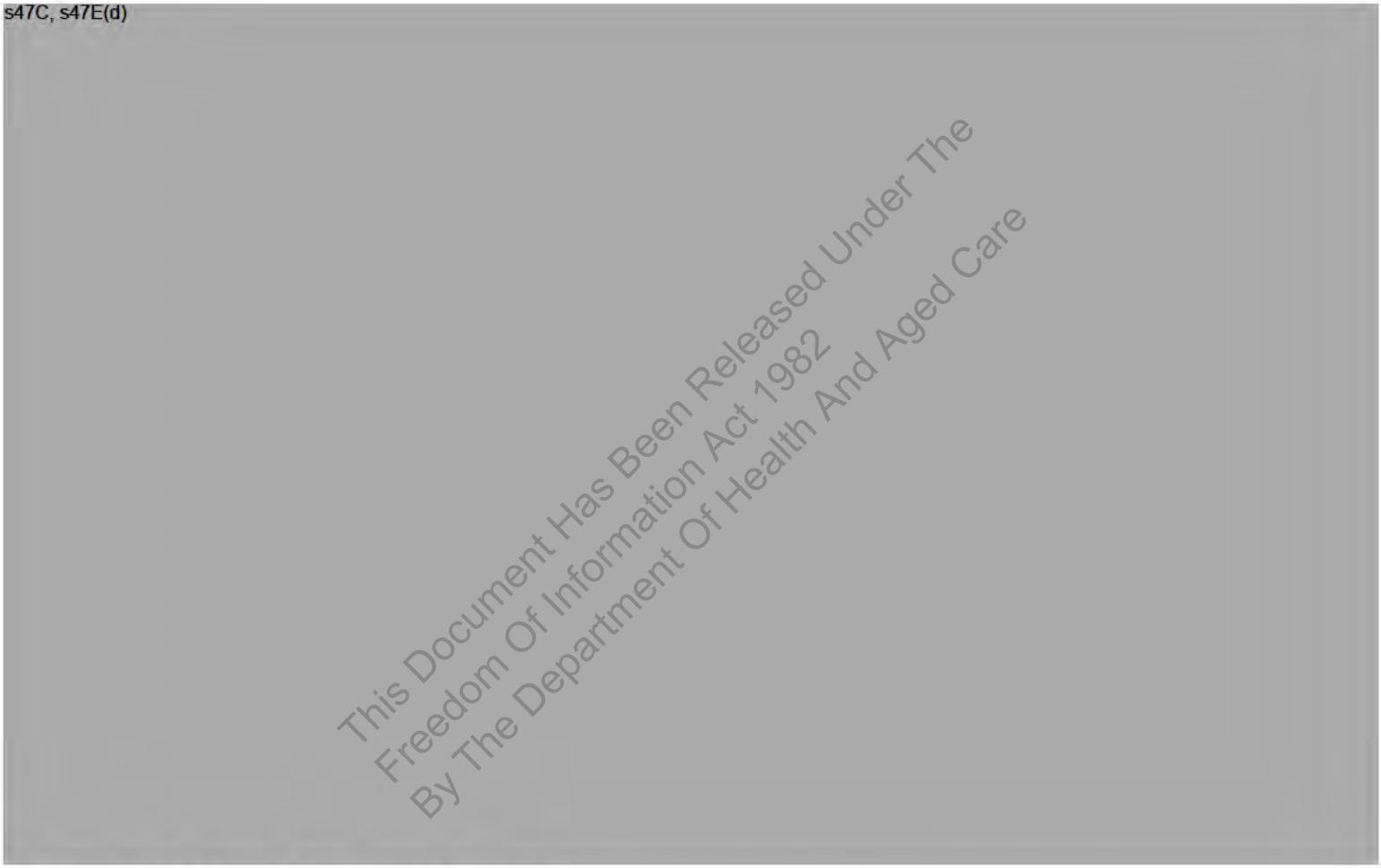
Are the new items a replacement of current items? Please provide relevant detail.

s47C, s47E(d)

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

s47C, s47E(d)

s47C, s47E(d)



This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

** Item numbers are indicative, subject to final approval*
*** Greatest permissible gap ($98.70 from 1 November 2023) applied to out of hospital services.*

MBS Flow ons

(excluding flow ons to Bulk Billing Incentives, Medicare Safety Net and Extended Medicare Safety Net (EMSN) – see cover sheet for details)

Will changes have an impact on the utilisation of other MBS items? Provide information, assumptions

For example, new procedural item may require a pathology test or anaesthesia

Tick all boxes that apply. ***Double-click box to fill.***

- ☐ GP Consultation
- ☐ Pathology
- ☐ Diagnostic services
- ☐ Allied Health
- ☐ Specialist Consultation
- ☐ Surgical procedure
- ☒ Diagnostic Imaging
- ☐ Non-surgical procedure

Type:

☐ Dental Type:
☐ Other Type:

Item 61505 (CT for anatomic localisation or attenuation correction). No change to item however this item will be co-claimed with the new whole body PSMA PET item.

MBS Off sets

Are the new items a substitute for an existing item? If yes, provide any available information or assumptions around the percentage substitution.

Are the new items a replacement of current items? Please provide relevant detail.

For example, will the introduction of a longer consultation item for GPs impact on the number of patients seen

Tick all boxes that apply. ***Double-click box to fill.***

☐ GP Consultation ☐ Specialist Consultation ☐ Diagnostic Imaging
☐ Pathology ☐ Surgical procedure ☐ Non-surgical procedure
☐ Diagnostic services
☐ Allied Health Type:
☐ Dental Type:
☐ Other Type:

There are no anticipated offsets identified with these new items.

Part D: Costing Assumptions

Assumptions

Provide as much relevant detail as possible

Indicate if you require a number of scenarios, for example freezing the schedule fee for some items and indexing schedule fee for other items or increasing or decreasing schedule fee for some items

s47c, s47D

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

s47c, s47D

[redacted]

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Part E: Potential flow-on impact on PBS, DVA, MA or other program or portfolio

Pharmaceutical Benefits Scheme (PBS) *Contact program area to discuss.*	
Department of Veteran Affairs (DVA) *Liaisons with external agencies are formally conducted through MBD BMU*	
Medicare Australia (MA) *Program area to prepare an External Costing Request (ERC). Liaison with MA is formally conducted through MBD BMU*	
Other program or portfolio *Contact MBD BMU to discuss*	.

Part F: MBS Data and Analysis Request (if required)

Description of Request

(a) Any restrictions on data (only GPs, item numbers)

(b) Time period (financial year time series starting 2004-05, quarterly)

(c) Data required – services, benefits, number of GPs or patients

(d) Attach example of output tables if available

Note: If required, staff can generate reports from CasemixWiz (i.e. by DRG, public/private hospital splits). Please indicate your requirements below.

s22

From: s22
Sent: Friday, 16 August 2024 9:24 AM
To: s22
Cc: s22 Budget.Team.1
Subject: RE: Finance Queries - 2024-25 MYEFO - New & Amended - N&A6 PET and therapeutic medicine services for lutetium treatment [SEC=PROTECTED]

Hi s22

Great, this costing is correct, thanks.

s22

From: s22
Sent: Friday, 16 August 2024 8:19 AM
To: s22
Cc: s22 ; Budget.Team.1
Subject: RE: Finance Queries - 2024-25 MYEFO - New & Amended - N&A6 PET and therapeutic medicine services for lutetium treatment [SEC=PROTECTED]

Hi s22

Thanks for your all your help on this one.

Finance have agreed to the costs. Can you please review the attached to ensure it is correct?

Thanks!

Regards
s22
Budget Officer, Budget Team 1

Budget Strategy Branch | Health Systems Strategy Division | Health Strategy, First Nations & Sport Group
Australian Government Department of Health
T: 02 6289 s22 | E: s22 health.gov.au
Location: Sirius Building Level 6 South, 23 Furzer Street WODEN, ACT 2606

The Department of Health and Aged Care acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: s22 .Health.gov.au>
Sent: Wednesday, 7 August 2024 1:26 PM
To: s22 .Health.gov.au>; Budget.Team.1 s47E(d) .health.gov.au>
Cc: s22 d.Health.gov.au>; s22 s22 .Health.gov.au>; s22 .Health.gov.au>
Subject: RE: Finance Queries - 2024-25 MYEFO - New & Amended - N&A6 PET and therapeutic medicine services for lutetium treatment [SEC=PROTECTED]

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Hi s22

No worries. Hopefully this clarifies further with regard to your questions:

s47C, s47E(d)

Thanks,
s22

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

---

From: s22 .Health.gov.au>
Sent: Wednesday, 7 August 2024 11:57 AM
To: s22 .Health.gov.au>; Budget.Team.1 s47E(d) .health.gov.au>
Cc: s22 .Health.gov.au>; s22 s22 Health.gov.au>; s22 .Health.gov.au>
Subject: RE: Finance Queries - 2024-25 MYEFO - New & Amended - N&A6 PET and therapeutic medicine services for lutetium treatment [SEC=~~PROTECTED~~]

Hi s22

I'm just trying to understand this myself and I don't know much about the detail ☺. I just wanted to check, I understand this may be a new item on the MBS but by undertaking this new item would there be a reduction in another treatment item? Do patients maintain their existing treatment and this is on top of those?

Additionally, can you expand on the below in yellow by outlining why it is too difficult. I just want to provide a reasoning/justification to Finance, as I know the first question back will be why is it too difficult.

s47C, s47E(d)

Many thanks

s22
Assistant Director, Budget Team 1

From: s22 .Health.gov.au>
Sent: Wednesday, 7 August 2024 10:57 AM
To: s22 .Health.gov.au>; Budget.Team.1 s47E(d) .health.gov.au>
Cc: s22 .Health.gov.au>; s22 s22 .Health.gov.au>
Subject: RE: Finance Queries - 2024-25 MYEFO - New & Amended - N&A6 PET and therapeutic medicine services for lutetium treatment [SEC=PROTECTED]

Hi s22

Thanks for sending these through. We've responded to the questions in red text in the email below.

You will also have seen the revised costing earlier today from HERD, as there was an error in the initial costing with respect to indexation not being applied to the PET scan from 1 July 2027 onwards.

Please let us know if there are any further questions, happy to clarify.

Thanks,
s22

s22
Diagnostic Imaging Section
Diagnostic Imaging and Pathology Branch
Medical Benefits Division | Health Resourcing Group
Australian Government Department of Health And Aged Care
T: 02 6289 s22 | E: s22 @health.gov.au
GPO Box 9848, Canberra ACT 2601, Australia

The Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

From: s22 .Health.gov.au>
Sent: Tuesday, 6 August 2024 11:55 AM
To: s22 .Health.gov.au>; s22 s22 .Health.gov.au>; s22 .Health.gov.au>
Cc: s47E(d) .health.gov.au>
Subject: Finance Queries - 2024-25 MYEFO - New & Amended - N&A6 PET and therapeutic medicine services for lutetium treatment [SEC=PROTECTED]

Hi all,

I have received the following queries from Finance for N&A6 PET and therapeutic medicine services for lutetium treatment

s47C, s47E(d)

s47C, s47E(d)

This Document Has Been Released Under The
Freedom Of Information Act 1982
By The Department Of Health And Aged Care

Table 1: Service utilisation: initial and continuing Lutetium treatment for mCRPC (Items 16019 and 16020)

	Stage of treatment and percentage of patients continuing to next cycle	Year 1	Year 2	Year 3	Year 4	Year 5
Initial Lutetium treatment phase: Item 16019 (claimable up to two times)	s47C, s47E(d)					
Continuing Lutetium treatment phase: Item 16020 (claimable up to four times)						
Total number of Lutetium cycles per year		s47C, s47E(d)				

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Thanks

s22
Assistant Director, Budget Team 1
Budget Strategy Branch | Health Systems Strategy Division | Health Strategy, First Nations & Sport Group
Australian Government Department of Health
T: 02 6289 s22 E: s22 @health.gov.au
Location: Sirius Building Level 6 South, 23 Furzer Street WODEN, ACT 2606

The Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.

s22

From: s22
Sent: Wednesday, 12 June 2024 3:03 PM
To: s22
s22
Subject: FW: DUE 2PM TODAY: Urgent - New and Amended NPP for MYEFO [SEC=OFFICIAL]

Thanks everyone – there is still plenty of time between now and November/December for MYEFO…..

s22
Director, Diagnostic Imaging Section
Diagnostic Imaging and Pathology Branch | Medicare Benefits and Digital Health Division | Health Resourcing Group
Australian Government Department of Health and Aged Care
T: s22 | E: s22 @protected.health.gov.au |

PO Box 9848, Canberra ACT 2601, Australia

The Department of Health and Aged Care acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

From: s22
Sent: Wednesday, 12 June 2024 3:01 PM
To: s22
Cc: WARNER, Mary
Subject: RE: DUE 2PM TODAY: Urgent - New and Amended NPP for MYEFO [SEC=OFFICIAL]

s22

Apologies for the delay – this has not been through Mary - Diagnostic Imaging input is below

s47C

And Where did the change come from:

MSAC decision (Application 1686.1 – 177Lutetium Prostate Specific Membrane Antigen (PSMA) imaging and therapy (i&t) for metastatic, castrate resistant prostate cancer (mCRPC)) from April 2024.

Estimated start date:
1 July 2025

Cost/Save 2024/25 – 2027-28 (No TBA please – we need to have an estimate – even if really rubbery):
s47C

Minor and Machinery changes to the DIST

What is the change:
Minor and mechanical update to Diagnostic Imaging services:

- Enabling Nurse Practitioners to request specific services for patients at RACF.
- Updating requesting items for allied health practitioners to remove items which are non-requested items or items that have ceased.
- Amending certain diagnostic radiology (x-ray) services to include 'missing' combination of contiguous anatomical areas which will provide clarity about which areas of the body they cover.

And Where did the change come from:
Dept.

Estimated start date:
1 July 2025

Cost/Save 2024/25 – 2027-28 (No TBA please – we need to have an estimate – even if really rubbery):
Estimated cost is cost neutral.

s22

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

s22 [redacted]

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

s22 [redacted]
Director, Diagnostic Imaging Section
Diagnostic Imaging and Pathology Branch | Medicare Benefits and Digital Health Division | Health Resourcing Group
Australian Government Department of Health and Aged Care
T: s22 [redacted] | E: s22 [redacted] .health.gov.au |

PO Box 9848, Canberra ACT 2601, Australia

The Department of Health and Aged Care acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

From: s22 [redacted] .Health.gov.au>
Sent: Wednesday, 12 June 2024 11:48 AM
To: s22 [redacted] .Health.gov.au>; s22 [redacted]
s22 [redacted] .Health.gov.au>; s22 [redacted] .Health.gov.au>; s22 [redacted]
s22 [redacted] .Health.gov.au>; s22 [redacted] .Health.gov.au>;
s22 [redacted] .Health.gov.au>; s22 [redacted]
s22 [redacted] .Health.gov.au>; s22 [redacted] .Health.gov.au>; s22 [redacted]

s22 .Health.gov.au>; s22 .Health.gov.au>;
s22 .Health.gov.au>; s22 s47E(a) .Health.gov.au>;
s22 s47E(a) .Health.gov.au>; s22
s22 ealth.gov.au>
Cc: MURRAY, Nigel s22 .Health.gov.au>; RILEY, Louise
s22 Health.gov.au>; WARNER, Mary s22 Health.gov.au>;
s22 .Health.gov.au>
Subject: DUE 2PM TODAY: Urgent - New and Amended NPP for MYEFO [SEC=OFFICIAL]
Importance: High

Hi everyone

Apologies for the tight turnaround on this request.

Please see request below re: **New and Amended NPP for MYEFO.**

I have created a document to provide your input, by 2.00 today please.

Info will need to include:

What is the change:
Where did the change come from – MRAC, MSAC, MBS Taskforce, Dept
Estimated start date
Cost/Save 2024/25 – 2027-28. No TBA please – we need to have an estimate – even if really rubbery.

Need to include LARCs, anything we know that is in the MSAC pipeline (including the ones that Min will have delegation for from 1 July as we'll still need to include in MYEFO as part of the overall spend), tranche 2 for 75/85 (only if we think we can make it happen), and anything else…

Appropriate caveats will be put on the info – re changes still need to go through costing process etc.

Thanks
s22

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

s22
Executive Officer to Daniel McCabe | First Assistant Secretary

Medicare Benefits & Digital Health Division | Health Resourcing Group
Australian Government Department of Health and Aged Care
T: 6289 s22 E: s22 .Health.gov.au

Date Received by Services Australia Costing Team:		Costing Reference Number:	

EXTERNAL COSTING REQUEST

Please use this form when seeking a formal costing from the Services Australia.

A formal costing is required when Services Australia is requested to deliver new, or change existing, services under a government budget measure or a contract invoicing arrangement (Retained Receipts).

Section One
PROPOSAL DETAILS
(requesting agency to complete)

Section 1.1 – Proposal Overview

Title of the Proposal	^{177}Lutetium PSMA treatment for metastatic castrate resistant prostate cancer, including diagnostic whole body PSMA PET scan to determine eligibility for treatment.	
Requesting/Lead Agency	Department of Health and Aged Care	
Requesting Agency Contact Officer. *Please nominate a contact officer who will be available for questions while the proposal is being costed.*	Name:	s22 (M-Wed, Friday) s22 (M-Tues, Thurs-F).
	Phone Number:	s22 (02) 5132 s22 (02) 5132 s22
	Email:	s22 health.gov.au s22 health.gov.au
Request Authorised by (from requesting agency - SES B1 minimum)	Name:	s22 for Mary Warner (authorising responsibility delegated from the Assistant Secretary, Diagnostic Imaging and Pathology Branch)
	Position:	Director, Diagnostic Imaging Section
	Phone Number:	02 5162 s22
Implementation Date (This is the date by which the proposal must be delivered.)	1 July 2025	*What is the driver/imperative for this delivery date? Please note that reasonable timeframes are required in order to implement proposals. For proposals requiring an ICT solution, please allow a minimum of 6 months lead time.*
Date costing is required		*Please provide a reason for the due date if less than the standard timeframe of 10 working days. E.g. Cabinet Submission due.*
Executive Summary of the Proposal	s47C [redacted]	

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

	s47C [redacted]

Section 1.1- Proposal Overview (continued)

Method of Funding *(Will Services Australia receive Appropriation from Government? Or be required to enter into an invoicing arrangement with the partner agency to obtain funding?)*	Appropriation		
	If Appropriation, which Budget Round?		MYEFO 2024-2025
Life of the Proposal?	Ongoing	If terminating, please provide termination date:	
New policy, new work or Change Request?	New policy		
Has this been costed previously?	No	If yes, please provide previous costing reference number or when it was completed.	
Is Legislation required? If yes, which legislation/legislative instrument will require amendment?	GMST, DIST	If yes, when is legislation expected to be tabled before parliament?	Regulations will be subject to parliamentary scrutiny once registered on the federal register of legislation following consideration at executive council. The amendment regulations will be registered prior to commencement of the changes.
		Are there possible difficulties with the passage of legislation?	No

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Section 1.2 - Proposal Details

When filling out this section please consider the following:

Claiming/registering/processing:
Registration (new or existing)
Online functionality
Limitations e.g. claim once per year
Data transfer
Migration of existing data

End user:
Eligibility
Enquiries handling
Target audience

Payment:
Processing requirements
Frequency of payments
Limitations e.g. payment cap
Statements (new or existing)
Changes to assessment/collection

Compliance:
Audit requirements
Frequency
Risks
Take-up rates

Other:
Legislation changes
Schedule changes
Third party involvement e.g. software vendor
Communication of proposal
Stakeholder engagement
Web-based solution required?

Proposal Details (include underlying policy assumptions and perceived benefits)	This change will create three new MBS items: s47C, s47E(d) [redacted]

(Note: the Greatest Permissible Gap will apply to out of hospital services).

s47C, s47E(d)

[redacted]

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

** Item numbers are indicative, subject to final approval*

	s47C, s47E(d)

Section 1.2 - Proposal Details (continued)

Deregulation Agenda Will this proposal result in additional regulatory impact for individuals, businesses and/or community organisations? Please provide details of the impact and offsetting arrangements.	N/A
Risks (including mitigation strategies)	None identified
Payments Affected	N/A
Reporting Requirements	There are no reporting requirements over and above the existing MBS reporting requirements.
Impact of the proposal upon other agencies	Possible impact on Department of Veterans' Affairs.

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Section 1.3 - Processing Volumes and/or Customer Cohort Numbers

Some proposals are volume based such as PBS changes. Some proposals may impact on customer numbers such as Aged Pension payment recipients. Put those numbers in this section.

- *It is understood that volume/customer information may only be available during the costing process. Please forward on this information as soon as it becomes available*

- *Requesting agencies may wish to attach relevant data models to indicate volumes*

Please see attached costing summary

Volumes / Customer Cohorts	2023-24	2024-25	2025-26	2026-27	2027-28
Volumes will be provided with the Department of Health budget costing					
Flow on consequences to other customer cohorts/processing and other volumes					
Nil					

Section Two
Services Australia CONTACTS, ENDORSEMENTS AND ASSUMPTIONS
(Services Australia to complete)

Section 2.1 – Services Australia contact details and endorsements

Services Australia Business Owner Details

Services Australia Contact Officer	Name:	
Please nominate a contact officer who will be available for questions while the proposal is being costed.	Phone Number:	
	Branch:	
	Positional email:	

Services Australia Endorsements

The below endorsements are required for a costing to proceed. However, please submit the External Costing Request form as soon as possible even if Lead ICT GM endorsement has not yet been obtained.

Endorsed by:	Lead ICT General Manager	Business Owner National Manager
Name		
Division or Branch		
Signature: *(email authorisation will be accepted)*		

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

	SES B2 minimum	SES B1 minimum
Date:		

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Section 2.2 – Services Australia Business Assumptions	
NOTE: External Costing Requests received by Services Australia must not be distributed to Services Australia positional/shared mailboxes. Completed External Costing Request may only be distributed on a need-to-know basis.	
Internal Executive Summary	*To ensure costings are as timely and accurate as possible, please include sufficient information to enable stakeholders to understand how they will be affected by the new or changed process.* *For example, describe, in general terms, how the proposal will be implemented.* *Is this the most efficient delivery method for the agency? Does it support the agency's strategic direction?* *Should alternative delivery solutions be costed?* *Please consider:* • *appropriate delivery channels and the Service Delivery Reform agenda* • *aligning payments or services to the Service Delivery Operating model.*
Will this proposal:	
- amend an existing payment?	
- create new payments?	
- affect the review or appeal process?	
- affect debt raising/recovery activities?	
- require a new letter or a change to an existing letter?	*If so, which letters?* *Please provide the volume of letters to be sent by payment type.*
- please provide the volume of letters to be sent by payment type.	*If so, which forms or claim information booklets?*
- require a new form or a change to an existing form (including information booklets)?	*If so, which forms or claim information booklets?*
- require a mail out?	*Is this the most efficient delivery method? Should alternative delivery solutions be costed?*
- generate additional compliance activities?	*Design, development and evaluation of compliance activities to address identified risks.*
- affect Management Information deliverables?	*Will new or changed Management Information (MI) deliverables be required? Contact:* S47E(d) *for assistance.*

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

- require data collection/exchange with another agency?	

Subsection 2.2 (a) – Business Stakeholder Assumptions

Business Stakeholder assumptions will be provided to the Business Owner for clearance during the costing process. Subsection 2.2 (a) does not need to be completed prior to submitting the External Costing Request form.

Section 2.3 – Services Australia ICT Requirements (Business to complete)

ICT Requirements	*From a business perspective, what would you like ICT to deliver?* *Please also explain your business continuity requirements, thinking about the business impact if the ICT system is not operating – i.e. the business position on data loss, backup frequency, availability of system.*
Will the ICT functionality for this proposal be required for a defined period or ongoing? Will the ICT functionality for this proposal be delivered online?	*If defined period, estimate a date when ICT functionality will no longer be required.* *If delivered online it is a Legislative requirement that all web content conforms to the Web Content Accessibility Guidelines (WCAG) v2.0 at the Level AA standard. The Proposed ICT Solution must adhere to this requirement*
Is this a repeatable change?	*Yes/no*

Subsection 2.3 (a) – ICT Proposed Solution

The Proposed ICT Solution will be provided to the Business Owner at the end of the costing process. Subsection 2.3 (a) does not need to be completed before submitting the External Costing Request form.

Section 2.4 – Financial Summary

The Financial Summary will be provided to the Business Owner at the end of the costing process. Section 2.4 does not need to be completed before submitting the External Costing Request form.

Note: Costings are valid for a period of 6 months from the date the costing is finalised or until one month prior to the date work must commence, whichever is sooner.

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Section Three AUTHORISATIONS (requesting agency and Services Australia to complete)		
Services Australia - Authorisations:		
Authorised by:	**Business Assumptions Agreed**	**Costing Agreed**
Name		
Branch		
Phone		
Email		
Signature: *(email authorisation will be accepted)*	SES B1 minimum	SES B1 minimum
Date:		
Requesting Agency - Authorisations: The external agency also notes the timeframe required to implement this proposal.		
Authorised by:	**Business Assumptions Agreed**	**Costing Agreed**
Name		
Branch		
Phone		
Email		
Signature: *(email authorisation will be accepted)*	SES B1 minimum	SES B1 minimum
Date:		

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Section Four VERSION CHANGE CONTROL (requesting agency and Services Australia to complete)			
Version Number	**Date**	**Amended by**	**Brief description of the changes**

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Attachment A

s47C, s47E(d)

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Authorised Prescriber	Product Profile	Product Presentation	Number of New Patients	Number of Prescription or Devices
MAP23-0044452	Lutetium-177 Octreotate (177 Lu-DOTATATE)	Lutetium-177 Octreotate (177 Lu-DOTATATE)	0	0
MAP23-0044111	F18\18F-DCFPyL Prostate Specific Membrane Antigen (PSMA)	F18\18F-DCFPyL Prostate Specific Membrane Antigen (PSMA)	748	748
MAP23-0044142	Lutetium-177 Prostate Specific Membrane Antigen (PSMA)	Lutetium-177 Prostate Specific Membrane Antigen (PSMA)	0	0
MAP23-0044141	F18\18F-Sodium Fluoride (NaF)	F18\18F-Sodium Fluoride (NaF)	0	0

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Authorised Prescriber	Product Profile	Product Presentation	Number of New Patients	Number of Prescription or Devices
MAP23-0044452	Lutetium-177 Octreotate (177 Lu-DOTATATE)	Lutetium-177 Octreotate (177 Lu-DOTATATE)	0	0
MAP23-0044141	F18\18F-Sodium Fluoride (NaF)	F18\18F-Sodium Fluoride (NaF)	0	0
MAP23-0044111	F18\18F-DCFPyL Prostate Specific Membrane Antigen (PSMA)	F18\18F-DCFPyL Prostate Specific Membrane Antigen (PSMA)	409	409
MAP23-0044142	Lutetium-177 Prostate Specific Membrane Antigen (PSMA)	Lutetium-177 Prostate Specific Membrane Antigen (PSMA)	0	0

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Authorised Prescriber	Product Profile	Product Presentation	Number of New Patients	Number of Prescription or Devices
MAP23-0044142	Lutetium-177 Prostate Specific Membrane Antigen (PSMA)	Lutetium-177 Prostate Specific Membrane Antigen (PSMA)	1	1
MAP23-0044111	F18\18F-DCFPyL Prostate Specific Membrane Antigen (PSMA)	F18\18F-DCFPyL Prostate Specific Membrane Antigen (PSMA)	929	929
MAP23-0044452	Lutetium-177 Octreotate (177 Lu-DOTATATE)	Lutetium-177 Octreotate (177 Lu-DOTATATE)	0	0
MAP23-0044141	F18\18F-Sodium Fluoride (NaF)	F18\18F-Sodium Fluoride (NaF)	0	0

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Australian Government
Department of Health and Aged Care

Information Brief
MB24-000685
Version (1)
Date sent to MO: 15/04/2024

To: **Minister Butler**

Subject: **DEPT. INITIATED BRIEF: OUTCOMES OF THE MEDICAL SERVICE ADVISORY COMMITTEE MEETING 4-5 APRIL 2024**

Comments:			
Contact Officer:	*Caroline Turnour*	*Assistant Secretary, Office of Health Technology Assessment*	Ph: (02) 6289 s22 Mobile: s22
Clearance Officer:	*Adriana Platona*	*First Assistant Secretary, TAAD*	Ph: (02) 6289 s22 Mobile: s22

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Key Issues:

1. The Medical Services Advisory Committee (MSAC) considered 14 applications at its April 2024 meeting. A summary table of the applications, by MSAC recommendation (support, defer, not support), is provided in **Attachment A.**

2. Overall, 71% (10 out of 14) of submissions considered at the April 2024 meeting received a positive recommendation. This is higher than the 51% supported between 2018-2023.

3. This is the first meeting held under the new MSAC Chair, Professor Jonathan Craig. You may wish to have a meeting to discuss the meeting outcomes directly with him.

Background:

The MSAC meets three times per year, usually in March, July, and November, and provides advice to you on applications seeking public funding based on assessment of comparative safety clinical effectiveness, cost-effectiveness, and total cost, using the best available evidence.

Next Steps:

Applicants will be informed, via email, of the MSAC high level outcome on Wednesday, 17 April 2024 following confirmation of agreement that applicants will not disclose the outcome prior to its publication on the MSAC website.

The ratified Public Summary Documents (PSDs) with full details of the consideration, including any conditions or circumstances under which an application was supported, and reasons for deferral or rejection are provided to applicants six to eight weeks after the meeting.

Applicants who receive a deferred or not supported recommendation may request a post-MSAC meeting with the Department of Health and Aged Care following receipt of the ratified PSD to further their understanding of the reasons for the MSAC recommendation.

The PSDs are published on the MSAC website eight to ten weeks after the MSAC meeting.

Budget/financial implications will be provided in the implementation policy proposals.

Attachments:

A: April 2024 MSAC meeting high level outcomes

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

s22

This Document Has Been Released Under The
Freedom Of Information Act 1982
By The Department Of Health And Aged Care

s22

This Document Has Been Released Under The
Freedom Of Information Act 1982
By The Department Of Health And Aged Care

MSAC Application	Applicant	MSAC advice	Summary outcomes – rationale, next steps and sensitivities
1686.1 – ^{177}Lutetium PSMA i&t for metastatic castrate resistant prostate cancer	A Group of academic specialists, co-sponsored by the Australian Association of Nuclear Medicine Specialists (AANMS)	**Support**	On the basis of the current evidence and provided the applicants have a legal right to use ^{177} lutetium prostate-specific membrane antigen imaging scan and therapy (^{177}Lu PSMA i&t) in Australia, MSAC supported the creation of new Medicare Benefits Schedule (MBS) items for 1) ^{177}Lu PSMA i&t for treatment of progressive metastatic castrate resistant prostate cancer (mCRPC) and 2) whole body PSMA positron emission tomography/computed tomography (PSMA PET/CT) to identify those eligible for ^{177}Lu PSMA i&t. MSAC reconsidered the evidence comparing ^{177}Lu PSMA i&t and ^{177}Lu PSMA-617 products. MSAC reaffirmed previous conclusions that the two products are noninferior and thus considered the evidence for ^{177}Lu PSMA-617 to be relevant for ^{177}Lu PSMA i&t. Thus, MSAC accepted the high certainty from the evidence that ^{177}Lu PSMA i&t therapy is acceptably safe and effective. MSAC considered that its previous uncertainties regarding the economic and financial analyses had been resolved sufficient for decision making. Despite limitations in the revised economic evaluation, MSAC was satisfied the incremental cost-effectiveness ratio (ICER) range provided reliable estimates for the upper limit of cost-effectiveness of ^{177}Lu PSMA i&t over its comparators of best supportive care and cabazitaxel. Although the ICER was high, MSAC accepted that ^{177}Lu PSMA i&t was cost effective in the context of a population with high clinical need, consumer preference for ^{177}Lu PSMA therapy over its comparators and an equity of access issue as some patients are currently paying for the treatment privately or the treatment is funded through the Department of Veterans' Affairs. MSAC also considered that the financial impact was acceptable for this well-defined population. MSAC noted the patent related issues raised during the consultation process. MSAC referred to its Terms of Reference and concluded that patent related matters would require consideration by government prior to any decision to list the MBS items as a result of this application.

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

s22

This Document Has Been Released Under The
Freedom Of Information Act 1982
By The Department Of Health And Aged Care

s22

This Document Has Been Released Under The
Freedom Of Information Act 1982
By The Department Of Health And Aged Care

s22

This Document Has Been Released Under The
Freedom Of Information Act 1982
By The Department Of Health And Aged Care

s22

This Document Has Been Released Under The
Freedom Of Information Act 1982
By The Department Of Health And Aged Care

s22

This Document Has Been Released Under The
Freedom Of Information Act 1982
By The Department Of Health And Aged Care

s22

This Document Has Been Released Under The
Freedom Of Information Act 1982
By The Department Of Health And Aged Care

s22

This Document Has Been Released Under The
Freedom Of Information Act 1982
By The Department Of Health And Aged Care

s22

This Document Has Been Released Under The
Freedom Of Information Act 1982
By The Department Of Health And Aged Care

s22

This Document Has Been Released Under The
Freedom Of Information Act 1982
By The Department Of Health And Aged Care

s22

This Document Has Been Released Under The
Freedom Of Information Act 1982
By The Department Of Health And Aged Care

Australian Government

Department of Health and Aged Care

Information Brief
MB24-002917
Version (1)
Date sent to MO: 12/11/2024

To: Minister Butler

Subject: INFORMATION BRIEF - SUPPORTING PATIENTS TO ACCESS LUTETIUM PROSTATE THERAPY

Comments:			
Contact Officer:	*Mary Warner*	*Assistant Secretary, Medicare Benefits and Medical Health Division*	Ph: (02) 5132 s22 Mobile: s22
Clearance Officer:	*Daniel McCabe*	*First Assistant Secretary, Medicare Benefits and Medical Health Division*	Ph: (02) 5132 s22 Mobile: s22

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Novartis approach to interim Pluvicto access (commercially sensitive)

Novartis have submitted a draft approach for the interim "bridging" access to Pluvicto in Australia, pending a health technology assessment (HTA), which is provided in **Attachment A**.

To proceed with this approach, Novartis has requested from the Australian Government that:

1. The MBS items recommended for public funding by MSAC in Application 1686.1 be deferred and this be communicated to stakeholders.
2. It provides funding for nationally reimbursed access to Pluvicto – ahead of an assessment - and that interim access be capped, time-bound and **linked to certainty of a viable access pathway.**

The Department is meeting with Novartis on 13 November 2024 to discuss these issues.

Overview and key points:

1. The Department advises against Novartis' request to defer the inclusion 177Lutetium PSMA (Lutetium) treatment of metastatic castrate-resistant prostate cancer (mCRPC) on the Medicare Benefits Scheme (MBS). This recommendation applies universally to all forms of Lutetium, including i&t (locally compounded Lutetium) as well as Pluvicto, with the proposed implementation date being **1 July 2025**.

2. The Medical Services Advisory Committee (MSAC) evaluated Lutetium treatment for patients with metastatic castration-resistant prostate cancer (mCRPC) in Australia under MSAC Application 1686.1. The committee advised that the Australian Government introduce a Medicare Benefits Schedule (MBS) item for Lutetium treatment due to its clinical efficacy for the designated patient group and recommended a schedule fee deemed cost-effective for public funding.
3. Lutetium therapy has been available in Australia for over a decade, and there will be significant pressure on the Government to ensure that this treatment remains accessible to patients.
4. Novartis has not disclosed the price at which they would supply Pluvicto in Australia. However, it is likely significantly more than the price recommended by MSAC.
5. The Department strongly advises Novartis to submit an application to either the Medical Services Advisory Committee (MSAC) or the Pharmaceutical Benefits Advisory Committee (PBAC) for their product. This submission will allow the product to undergo a thorough evaluation through the established Australian Health Technology Assessment (HTA) process, ensuring that the proposed price is deemed cost-effective for Australian taxpayers before being recommended to the Government. At this stage Novartis advises that they might lodge an application at some stage in 2025.

Next steps:

- s42 [redacted]

s47C [redacted]

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

s47C [redacted]

Key risks:

- s47C [redacted]

Background:

- In April 2024 the MSAC recommended public funding for Lutetium therapy for patients with metastatic castrate-resistant prostate cancer (Application 1686.1), with an MBS schedule fee of $8,000/cycle (maximum of 6 cycles per patient).
- Lutetium has been manufactured in Australia via a generic product for over 10 years, through established processes using non-Therapeutic Goods Administration (TGA) approved radiopharmaceuticals available through clinical trials, and the TGA Special Access Scheme (SAS)/Authorised Prescriber (AP) pathways.
- The local production of radiopharmaceuticals is commonplace in Australia, and nuclear medicine facilities supply these products with the necessary standards of safety and quality. The approach of the radiopharmaceutical compounding industry and associated legislation through the TGA (which provides exemptions for this to occur in defined circumstances) is quite unique to Australia.
- On 17 July 2024 the TGA approved Pluvicto, a product containing Lutetium PSMA which is distributed by Novartis Pty Ltd (Novartis) for the treatment of metastatic prostate cancer, on the Australian Register of Therapeutic Goods (ARTG).
- The TGA subsequently advised that manufacturing Lutetium through a compounded radiopharmaceutical process was no longer an option for Australian facilities. TGA is looking at alternate regulatory options to allow continued use.
- Additionally, Novartis updated the patents relating to Pluvicto in mid-2024 which in their view, has made it illegal for a generic version to be manufactured and supplied in Australia. This claim has not been tested through the legal system.

s42 [redacted]

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

s47C [redacted]

General points and information:

Quality of the Australian health technology assessment process

- The MSAC is an independent committee which advises on new medical technologies and procedures for public funding through the MBS.
- MSAC undertakes rigorous and transparent HTA of MSAC applications and their advice to the Australian Government is independent of pharmaceutical and medical device manufacturers.
- MSAC recommendations are evidence based and MSAC maintains high ethical standards, including transparency of decision-making.
- MSAC recommendations are advisory in nature to the Australian Government and are integral to funding decisions made in the context of the Federal Budget.

Quality of the Australian health technology assessment process

- Australian radiopharmaceutical production involves safe products made in hospitals by highly trained professionals operating under regulations in line with the TGA regulations and State and Territory regulations.
- These products should be referred to as “compounded radiopharmaceuticals” and not as “homebrew”, which is not reflective of the high standards of safety and quality of the product.

s47C [redacted]

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

s47C

s47C

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Attachments:

Attachment A – Correspondence from Novartis - approach to interim access to Pluvicto in Australia.

Minister	**Minister Butler**
PDR Number	**MB24-002917**
Subject	****URGENT** Due to MPS by 3:30PM TODAY, 11/11** Information Brief - Supporting patients to access lutetium prostate therapy**
Contact Officer	Mary Warner 02 5132 s22 s22
Clearance Officer	Daniel McCabe 02 5132 s22 s22
Division/Branch	|Health Resourcing| Medicare Benefits & Digital Health
Has Budget Branch been consulted if there are financial implications?	Not Applicable

Adviser/DLO comments:	Returned to Dept for: REDRAFT ☐ NFA ☐

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

s22

From: s47F
Sent: Wednesday, 24 July 2024 2:50 PM
To: s22
Cc: s47F
Subject: RE: Potential start date for lutetium treatment items recommended by MSAC [SEC=OFFICIAL]

Hi s22

A 1 July 2025 start date would be fine if you got authority at MYEFO. If it didn't go through until Budget then we might be able to make 1 November 2025 work, although our preference is for 1 March 2026.

Cheers,
s47F

From: s22
Sent: Wednesday, July 24, 2024 10:14 AM
To: s47F
Cc: s47F
Subject: Potential start date for lutetium treatment items recommended by MSAC [SEC=OFFICIAL]

Hi s47F 😊

Another email!

MSAC recommended the listing of lutetium therapy for patients with prostate cancer at their April meeting (Application 1686.1) – it includes a new PET item in the DIST, and two new therapeutic nuclear medicine items in the GMST.

We are progressing work on costings and consultation, and are anticipating (hopefully) that it will be included in MYEFO 2024-2025. We are looking at start dates for these items and would appreciate your advice on what is possible. We have been thinking of 1 July 2025, however understand it may not fit into that timeframe for the work needed to be completed, in which case what implementation date would you advise? (if we get policy authority in MYEFO)

If it is not included in MYEFO it would need to be picked up in budget instead and subsequently a later start date.

Thanks,
s22

s22 ***(she/her)***
Diagnostic Imaging Section
Work days: Monday, Tuesday, Wednesday, Friday

Diagnostic Imaging and Pathology Branch | Medicare Benefits and Digital Health Division
Australian Government Department of Health and Aged Care
T: 02 5132 s22 | E: s22 @health.gov.au
GPO Box 9848, Canberra ACT 2601, Australia

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

This Document Has Been Released Under The Freedom of Information Act 1982 By The Department Of Health And Aged Care

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

s22

From: s22
Sent: Friday, 31 May 2024 3:03 PM
To: s47F
Cc: s47F
Subject: RE: Consultation materials for 1686.1 and 1562 for when PSD is published [SEC=OFFICIAL]

Thanks – good to go.

We should also consult with SA and DVA (good habit particularly as we move to use the Ministers delegation more – I know these two are not delegation but good habit).

Regards

s22
Director – Diagnostic Imaging Section

Diagnostic Imaging and Pathology Branch

Medicare Benefits and Digital Health Division | Health Resourcing Group
Australian Government Department of Health and Aged Care
T: 02 5162 s22 | E: s22 @health.gov.au
Location: Sirius Building 8.S.134
PO Box 9848, Canberra ACT 2601, Australia

The Department of Health and Aged Care acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

From: s22
Sent: Friday, May 31, 2024 2:56 PM
To: s22
Cc: DIMSAC ; s22
Subject: FW: Consultation materials for 1686.1 and 1562 for when PSD is published [SEC=OFFICIAL]

Hi s22

Please see draft email and attachment for consultation of the new theragnostic and PET items for your clearance.

This email will go out as soon as PSDs are published to the list of stakeholders provided below, we are targeting expertise in nuclear medicine, PET and cancer services.

Stakeholders will have 6 weeks to respond. We will also consult with compliance (incl PHI and AskMBS) as the same time.

When we receive all feedback, we will collate in a table and make any necessary amendments, then seek s22 advice before progressing descriptors and feedback table to you.

s22

Draft email (and attached word doc with item description for consultation)

Dear XXXX

The Department of Health and Aged Care is consulting on item descriptions for several new diagnostic imaging item which were recommended by the Medical Services Advisory Committee (MSAC) at their 4-5 April 2024 meeting, following their consideration of the two applications below.

The MSAC Public Summary Documents, which outline the MSAC decision regarding these applications, have now been published and are available online:

- Application 1562 – Streamlining Medicare Benefits Schedule items for PET Project: initial staging and restaging (including treatment response assessment and suspected recurrence) of all FDG-avid cancers
- Application 1686.1 – ^{177}Lutetium PSMA i&t for metastatic castrate resistant prostate cancer

We would be grateful if your organisation could consider the proposed items in the attached document and provide feedback on their utility and any suggested changes.

Your advice on the proposed services will assist with implementation of the items should the Government support their listing.

Please provide your feedback to dimsac@health.gov.au by DD MMMM 2024.

Kind regards,
XXXX

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Stakeholder list:

Organisation	Contact email
Australian College of Rural and Remote Medicine (ACRRM)	acrrm@acrrm.org.au
Australian Diagnostic Imaging Association (ADIA)	secretariat@adia.asn.au, s47F @adia.asn.au s47F @adia.asn.au
Australian Medical Association (AMA)	ama@ama.com.au
Australian Society of Medical Imaging and Radiation Therapy (ASMIRT)	info@asmirt.org
Australian Association of Nuclear Medicine Specialists (AANMS)	aanms@aanms.org.au, president@aanms.org.au, generalmanager@aanms.org.au
Australia and New Zealand Society of Nuclear Medicine (ANZSNM)	secretariat@anzsnm.org.au
Prostate Cancer Foundation of Australia	s47F @pcfa.org.au, enquiries@pcfa.org.au
Cancer Council Australia	info@cancer.org.au
Clinical Oncology Society of Australia (COSA)	cosa@cancer.org.au
Medical Oncology Group of Australia (MOGA)	moga@moga.org.au
Private Cancer Physicians of Australia	pcpa@amaq.com.au
Urological Society of Australian and New Zealand (USANZ)	communication@usanz.org.au
Australian Genomic Cancer Medicine Centre (Garvan Institute)	director@garvan.org.au
Consumer Health Forum (CHF)	info@chf.org.au
Rural Alliance for Nuclear Scintigraphy (RAINS)	president@rains.asn.au

Royal Australasian College of Physicians (RACP)	racp@racp.edu.au
Royal Australasian College of Surgeons (RACS)	college.sec@surgeons.org reception.desk@surgeons.org
Royal Australian and New Zealand College of Radiologists (RANZCR)	ranzcr@ranzcr.edu.au, s47F @ranzcr.edu.au, s47F @ranzcr.edu.au
Royal Australian College of General Practitioners (RACGP)	racgp@racgp.org.au

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Australian Government

Department of Health and Aged Care

New Medicare Benefits Scheme (MBS) items for consultation – theranostic and diagnostic imaging services

Guidance for your consultation response:
Please read the document below and in the spaces provided include your comments and suggested amendments (where applicable). Your advice regarding all components of a proposed service is sought, such as:

- the utility of the item description in clinical practice as a requestor and/or provider of this proposed service,
- the appropriateness of the requesting and provider requirements, and
- the suitability of the proposed schedule fee (if an alternative fee is suggested, please validate this suggestion with a justification for why this fee is more appropriate, and where possible, provide a breakdown of costs).

Application 1686.1: ^{177}Lutetium PSMA i&t for metastatic castrate resistant prostate cancer

New items for the treatment of progressive or symptomatic metastatic castrate resistant prostate cancer in patients who have received at least one androgen receptor signalling inhibitor as well as at least one line of chemotherapy (docetaxel +/- cabazitaxel).

- **Draft Items 1-2 and explanatory note:** draft therapeutic intervention ^{177}Lutetium (Lu) prostate specific membrane antigen (PSMA) for initial and continuing treatment, for which treatment eligibility is determined by
- **Draft Item 3:** A diagnostic whole body PSMA positron emission tomography/computerised tomography (PET/CT) scan.

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Draft Item 1: Lu PSMA initial treatment item

Category 3 – Therapeutic procedures T3 – Therapeutic Nuclear Medicine
Item 16019 Administration of Lutetium 177 PSMA followed 24 hours later by whole body Lu-PSMA single-photon emission computed tomography (SPECT) for treatment of a patient with metastatic castrate resistant prostate cancer, who is PSMA-positive as determined by PSMA PET (defined as SUVmax >15 at a single site of disease and SUVmax >10 at all sites of measurable disease) after progressive disease has developed while on at least one taxane chemotherapy and at least one androgen receptor signalling inhibitor. Eligible to claim once per cycle, to a maximum of 2 cycles in the initial treatment phase. Fee: $8,000.00 75% and 85% benefits will apply *Note: Item number is indicative, subject to final approval, and the fee is equivalent to a 1 July 2024 fee.*
Feedback:

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Draft Item 2: Lu PSMA continuing treatment item

Category 3 – Therapeutic procedures T3 – Therapeutic Nuclear Medicine
Item 16020 Administration of Lutetium 177 PSMA followed 24 hours later by whole body Lu-PSMA single-photon emission computed tomography (SPECT) for treatment of a patient with metastatic castrate resistant prostate cancer, if: • a service to which item 16019 has been provided; and • the patient must not have developed disease progression while receiving Lutetium 177 PSMA for this condition. Eligible to claim once per cycle, to a maximum of 4 cycles in the continuing treatment phase. Fee: $8,000.00 75% and 85% benefits will apply *Note: Item number is indicative, subject to final approval, and the fee is equivalent to a 1 July 2024 fee.*
Feedback:

Draft Explanatory Note for Lu PSMA continuing treatment item (YYYY):

Item 16020 – Lutetium PSMA continuing treatment item for the treatment of progressive or symptomatic metastatic castrate resistant prostate cancer (mCRPC) For Item 16020 disease progression is defined as: • a rise in PSA of > 2 ng/mL confirmed by two tests a minimum of two weeks apart, and/or • evidence of new soft tissue metastases on diagnostic computed tomography as per the Response Evaluation Criteria in Solid Tumours (RECIST) criteria, as published by the European Organisation for Research and Treatment of Cancer and available online at: RECIST (eortc.org)
Feedback:

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Draft Item 3: diagnostic whole body PSMA PET/CT scan to determine eligibility for Lu PSMA therapy.

Category 5 – Diagnostic Imaging Services Group I4 – Nuclear Medicine Imaging Subgroup 2 – PET
Item 61528 Whole body prostate specific membrane antigen (PSMA) positron emission tomography study, performed for the assessment of suitability for Lutetium 177 PSMA therapy in a patient with metastatic castrate resistant prostate cancer after progressive disease has developed while on at least one taxane chemotherapy and at least one androgen receptor signalling inhibitor. (R) (Anaes) Fee: $1,300.00 75% and 85% benefits will apply *Note: Item number is indicative, subject to final approval, and the fee is equivalent to a 1 July 2024 fee.*
Feedback:

Application 1562: fluorodeoxyglucose (FDG) PET for initial staging and restaging of all typically FDG-avid cancers

Proposed amendments to existing MBS Item 61612 and new Item 61614 (to be implemented for restaging of rare cancers on 1 November 2024), to extend coverage of these services to include initial staging and restaging (including treatment response assessment and recurrence) for all typically FDG-avid cancers.

- **Amendment to Item 61612 and explanatory note:** whole body FDG PET study for the initial staging of a typically FDG-avid cancer for a patient who is considered suitable for active therapy if there is at least a 10% likelihood that the PET study result will inform a significant change in management for the patient.
- **Amendment to Item 61614:** whole body FDG PET study, following initial therapy, for the evaluation of suspected residual, metastatic or recurrent cancer for a patient who is undergoing or is suitable for active therapy of a typically FDG-avid cancer.

Amendment to Item 61612 - PET for initial staging of all typically FDG-avid cancers

Note: red underlined text shows proposed text to be amended in the item description. Black strikethrough text shows proposed deletions to the current item description.

s47C

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Amendment to Item 61614 - PET for initial staging of all typically FDG-avid cancers

Note: Item 61614 will be implemented for rare and uncommon cancers from 1 November 2024, with the addotopma; expansion to include all FDG-avid cancers subject to Government consideration. Red underlined text shows proposed text to be amended in the item description. Black strikethrough text shows proposed deletions to current item description.

s47C

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

s22

From: DIMSAC
Sent: Tuesday, 9 July 2024 4:13 PM
To: racgp@racgp.org.au
Cc: DIMSAC
Subject: MBS consultation - proposed new items for lutetium therapy for selected populations and staging PET for all FDG-avid cancers - due COB 21 August 2024 [SEC=OFFICIAL]
Attachments: MSAC Recommendations - PET for common cancers and lutetium for metastatic castrate resistant prostate cancer - for consultation - July 2024.docx

Dear RACGP

The Department of Health and Aged Care is consulting on item descriptions for several new diagnostic imaging item which were recommended by the Medical Services Advisory Committee (MSAC) at their 4-5 April 2024 meeting, following their consideration of the two applications below.

The MSAC Public Summary Documents, which outline the MSAC decision regarding these applications, have now been published and are available online:

- Application 1562 – Streamlining Medicare Benefits Schedule items for PET Project: initial staging and restaging (including treatment response assessment and suspected recurrence) of all FDG-avid cancers
- Application 1686.1 – ^{177}Lutetium PSMA i&t for metastatic castrate resistant prostate cancer

We would be grateful if your organisation could consider the proposed items in the attached document and provide feedback on their utility and any suggested changes.

Your advice on the proposed services will assist with implementation of the items should the Government support their listing.

Please provide your feedback to s47E(d) @health.gov.au by **5pm on 21 August 2024.**

Kind regards,
s22

Diagnostic Imaging Section

Diagnostic Imaging and Pathology Branch | Medicare Benefits and Digital Health Division
Australian Government Department of Health and Aged Care
s47E(d) @health.gov.au
Canberra ACT 2601, Australia

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

s22

From: DIMSAC
Sent: Tuesday, 9 July 2024 4:11 PM
To: reception.desk@surgeons.org
Cc: DIMSAC
Subject: MBS consultation - proposed new items for lutetium therapy for selected populations and staging PET for all FDG-avid cancers - due COB 21 August 2024 [SEC=OFFICIAL]
Attachments: MSAC Recommendations - PET for common cancers and lutetium for metastatic castrate resistant prostate cancer - for consultation - July 2024.docx

Dear Royal Australasian College of Surgeons

The Department of Health and Aged Care is consulting on item descriptions for several new diagnostic imaging item which were recommended by the Medical Services Advisory Committee (MSAC) at their 4-5 April 2024 meeting, following their consideration of the two applications below.

The MSAC Public Summary Documents, which outline the MSAC decision regarding these applications, have now been published and are available online:

- Application 1562 – Streamlining Medicare Benefits Schedule items for PET Project: initial staging and restaging (including treatment response assessment and suspected recurrence) of all FDG-avid cancers
- Application 1686.1 – ^{177}Lutetium PSMA i&t for metastatic castrate resistant prostate cancer

We would be grateful if your organisation could consider the proposed items in the attached document and provide feedback on their utility and any suggested changes.

Your advice on the proposed services will assist with implementation of the items should the Government support their listing.

Please provide your feedback to s47E(d) @health.gov.au by **5pm on 21 August 2024.**

Kind regards,
s22

Diagnostic Imaging Section

Diagnostic Imaging and Pathology Branch | Medicare Benefits and Digital Health Division
Australian Government Department of Health and Aged Care
s47E(d) @health.gov.au
Canberra ACT 2601, Australia

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

s22

From: DIMSAC
Sent: Tuesday, 9 July 2024 4:10 PM
To: president@rains.asn.au
Cc: DIMSAC
Subject: MBS consultation - proposed new items for lutetium therapy for selected populations and staging PET for all FDG-avid cancers - due COB 21 August 2024 [SEC=OFFICIAL]
Attachments: MSAC Recommendations - PET for common cancers and lutetium for metastatic castrate resistant prostate cancer - for consultation - July 2024.docx

Dear RAINS

The Department of Health and Aged Care is consulting on item descriptions for several new diagnostic imaging item which were recommended by the Medical Services Advisory Committee (MSAC) at their 4-5 April 2024 meeting, following their consideration of the two applications below.

The MSAC Public Summary Documents, which outline the MSAC decision regarding these applications, have now been published and are available online:

- Application 1562 – Streamlining Medicare Benefits Schedule items for PET Project: initial staging and restaging (including treatment response assessment and suspected recurrence) of all FDG-avid cancers
- Application 1686.1 – ^{177}Lutetium PSMA i&t for metastatic castrate resistant prostate cancer

We would be grateful if your organisation could consider the proposed items in the attached document and provide feedback on their utility and any suggested changes.

Your advice on the proposed services will assist with implementation of the items should the Government support their listing.

Please provide your feedback to s47E(d) @health.gov.au by **5pm on 21 August 2024.**

Kind regards,
s22

Diagnostic Imaging Section

Diagnostic Imaging and Pathology Branch | Medicare Benefits and Digital Health Division
Australian Government Department of Health and Aged Care
s47E(d) @health.gov.au
Canberra ACT 2601, Australia

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

s22

From: DIMSAC
Sent: Tuesday, 9 July 2024 4:12 PM
To: ranzcr@ranzcr.edu.au; s47F
Cc: DIMSAC
Subject: MBS consultation - proposed new items for lutetium therapy for selected populations and staging PET for all FDG-avid cancers - due COB 21 August 2024 [SEC=OFFICIAL]
Attachments: MSAC Recommendations - PET for common cancers and lutetium for metastatic castrate resistant prostate cancer - for consultation - July 2024.docx

Dear RANZCR

The Department of Health and Aged Care is consulting on item descriptions for several new diagnostic imaging item which were recommended by the Medical Services Advisory Committee (MSAC) at their 4-5 April 2024 meeting, following their consideration of the two applications below.

The MSAC Public Summary Documents, which outline the MSAC decision regarding these applications, have now been published and are available online:

- Application 1562 – Streamlining Medicare Benefits Schedule items for PET Project: initial staging and restaging (including treatment response assessment and suspected recurrence) of all FDG-avid cancers
- Application 1686.1 – ^{177}Lutetium PSMA i&t for metastatic castrate resistant prostate cancer

We would be grateful if your organisation could consider the proposed items in the attached document and provide feedback on their utility and any suggested changes.

Your advice on the proposed services will assist with implementation of the items should the Government support their listing.

Please provide your feedback to s47E(d) @health.gov.au by **5pm on 21 August 2024.**

Kind regards,
s22

Diagnostic Imaging Section

Diagnostic Imaging and Pathology Branch | Medicare Benefits and Digital Health Division
Australian Government Department of Health and Aged Care
s47E(d) @health.gov.au
Canberra ACT 2601, Australia

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

s22

From: DIMSAC
Sent: Tuesday, 9 July 2024 4:11 PM
To: racp@racp.edu.au
Cc: DIMSAC
Subject: MBS consultation - proposed new items for lutetium therapy for selected populations and staging PET for all FDG-avid cancers - due COB 21 August 2024 [SEC=OFFICIAL]
Attachments: MSAC Recommendations - PET for common cancers and lutetium for metastatic castrate resistant prostate cancer - for consultation - July 2024.docx

Dear Royal Australasian College of Physicians

The Department of Health and Aged Care is consulting on item descriptions for several new diagnostic imaging item which were recommended by the Medical Services Advisory Committee (MSAC) at their 4-5 April 2024 meeting, following their consideration of the two applications below.

The MSAC Public Summary Documents, which outline the MSAC decision regarding these applications, have now been published and are available online:

- Application 1562 – Streamlining Medicare Benefits Schedule items for PET Project: initial staging and restaging (including treatment response assessment and suspected recurrence) of all FDG-avid cancers
- Application 1686.1 – ^{177}Lutetium PSMA i&t for metastatic castrate resistant prostate cancer

We would be grateful if your organisation could consider the proposed items in the attached document and provide feedback on their utility and any suggested changes.

Your advice on the proposed services will assist with implementation of the items should the Government support their listing.

Please provide your feedback to s47E(d) @health.gov.au by **5pm on 21 August 2024.**

Kind regards,
s22

Diagnostic Imaging Section

Diagnostic Imaging and Pathology Branch | Medicare Benefits and Digital Health Division
Australian Government Department of Health and Aged Care
s47E(d) @health.gov.au
Canberra ACT 2601, Australia

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

s22

From: DIMSAC
Sent: Tuesday, 9 July 2024 4:26 PM
To: s47F s47F @servicesaustralia.gov.au; s47F @servicesaustralia.gov.au; s47F @servicesaustralia.gov.au; s47F @servicesaustralia.gov.au
Cc: s47F
Subject: FYI ONLY - MBS consultation - proposed new items for lutetium therapy for selected populations and staging PET for all FDG-avid cancers [SEC=OFFICIAL]
Attachments: MSAC Recommendations - PET for common cancers and lutetium for metastatic castrate resistant prostate cancer - for consultation - July 2024.docx

Dear all

FYI ONLY – consultation for proposed new items for lutetium therapy for selected populations and staging PET for all FDG-avid cancers

We've begun consulting on the item descriptors for two new items for Lutetium treatment for patients with metastatic castrate resistant prostate cancer (including a PET scan for eligibility for Lutetium treatment), and amending the PET for rare cancer items to be available for patients with any FDG-avid cancer. These items were recommended for public funding by MSAC at their April 2024 meeting (see Application 1562 – Streamlining Medicare Benefits Schedule items for PET Project: initial staging and restaging (including treatment response assessment and suspected recurrence) of all FDG-avid cancers, and Application 1686.1 – ^{177}Lutetium PSMA i&t for metastatic castrate resistant prostate cancer for more info).

The listing of the items and implementation is subject to a decision of Government in the context of the budget, however we are intending to put forth a 1 July 2025 start date for consideration.

We've sent the attached document out with our consultation request to our stakeholders. We will be progressing work towards implementation in the meantime and will send on the Business Rules and External Costing Request in the near future. No action from you is required at this stage, however please do get in touch if needed.

Thanks,
s22

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Diagnostic Imaging Section

Diagnostic Imaging and Pathology Branch | Medicare Benefits and Digital Health Division
Australian Government Department of Health and Aged Care
s47E(d) @health.gov.au
Canberra ACT 2601, Australia

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

s22

From: DIMSAC
Sent: Tuesday, 9 July 2024 4:08 PM
To: communication@usanz.org.au
Cc: DIMSAC
Subject: MBS consultation - proposed new items for lutetium therapy for selected populations and staging PET for all FDG-avid cancers - due COB 21 August 2024 [SEC=OFFICIAL]
Attachments: MSAC Recommendations - PET for common cancers and lutetium for metastatic castrate resistant prostate cancer - for consultation - July 2024.docx

Dear Urological Society of Australia and New Zealand

The Department of Health and Aged Care is consulting on item descriptions for several new diagnostic imaging item which were recommended by the Medical Services Advisory Committee (MSAC) at their 4-5 April 2024 meeting, following their consideration of the two applications below.

The MSAC Public Summary Documents, which outline the MSAC decision regarding these applications, have now been published and are available online:

- Application 1562 – Streamlining Medicare Benefits Schedule items for PET Project: initial staging and restaging (including treatment response assessment and suspected recurrence) of all FDG-avid cancers
- Application 1686.1 – ^{177}Lutetium PSMA i&t for metastatic castrate resistant prostate cancer

We would be grateful if your organisation could consider the proposed items in the attached document and provide feedback on their utility and any suggested changes.

Your advice on the proposed services will assist with implementation of the items should the Government support their listing.

Please provide your feedback to s47E(d) @health.gov.au by **5pm on 21 August 2024.**

Kind regards,
s22

Diagnostic Imaging Section

Diagnostic Imaging and Pathology Branch | Medicare Benefits and Digital Health Division
Australian Government Department of Health and Aged Care
s47E(d) @health.gov.au
Canberra ACT 2601, Australia

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

s22

From: DIMSAC
Sent: Tuesday, 9 July 2024 4:00 PM
To: 'aanms@aanms.org.au'; s47F
Cc: DIMSAC
Subject: MBS consultation - proposed new items for lutetium therapy for selected populations and staging PET for all FDG-avid cancers - due COB 21 August 2024 [SEC=OFFICIAL]
Attachments: MSAC Recommendations - PET for common cancers and lutetium for metastatic castrate resistant prostate cancer - for consultation - July 2024.docx

Dear AANMS

The Department of Health and Aged Care is consulting on item descriptions for several new diagnostic imaging item which were recommended by the Medical Services Advisory Committee (MSAC) at their 4-5 April 2024 meeting, following their consideration of the two applications below.

The MSAC Public Summary Documents, which outline the MSAC decision regarding these applications, have now been published and are available online:

- Application 1562 – Streamlining Medicare Benefits Schedule items for PET Project: initial staging and restaging (including treatment response assessment and suspected recurrence) of all FDG-avid cancers
- Application 1686.1 – ^{177}Lutetium PSMA i&t for metastatic castrate resistant prostate cancer

We would be grateful if your organisation could consider the proposed items in the attached document and provide feedback on their utility and any suggested changes.

Your advice on the proposed services will assist with implementation of the items should the Government support their listing.

Please provide your feedback to s47E(d) @health.gov.au by **5pm on 21 August 2024.**

Kind regards,
s22

Diagnostic Imaging Section

Diagnostic Imaging and Pathology Branch | Medicare Benefits and Digital Health Division
Australian Government Department of Health and Aged Care
s47E(d) @health.gov.au
Canberra ACT 2601, Australia

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

s22

From: DIMSAC
Sent: Tuesday, 9 July 2024 3:55 PM
To: acrrm@acrrm.org.au
Cc: DIMSAC
Subject: MBS consultation - proposed new items for lutetium therapy for selected populations and staging PET for all FDG-avid cancers - due COB 21 August 2024 [SEC=OFFICIAL]
Attachments: MSAC Recommendations - PET for common cancers and lutetium for metastatic castrate resistant prostate cancer - for consultation - July 2024.docx

Dear Australian College of Rural and Remote Medicine

The Department of Health and Aged Care is consulting on item descriptions for several new diagnostic imaging item which were recommended by the Medical Services Advisory Committee (MSAC) at their 4-5 April 2024 meeting, following their consideration of the two applications below.

The MSAC Public Summary Documents, which outline the MSAC decision regarding these applications, have now been published and are available online:

- Application 1562 – Streamlining Medicare Benefits Schedule items for PET Project: initial staging and restaging (including treatment response assessment and suspected recurrence) of all FDG-avid cancers
- Application 1686.1 – ^{177}Lutetium PSMA i&t for metastatic castrate resistant prostate cancer

We would be grateful if your organisation could consider the proposed items in the attached document and provide feedback on their utility and any suggested changes.

Your advice on the proposed services will assist with implementation of the items should the Government support their listing.

Please provide your feedback to s47E(d) @health.gov.au by **5pm on 21 August 2024.**

Kind regards,
s22

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

s22

From: DIMSAC
Sent: Tuesday, 9 July 2024 3:56 PM
To: secretariat@adia.asn.au; s47F @adia.asn.au; s47F @adia.asn.au
Cc: DIMSAC
Subject: MBS consultation - proposed new items for lutetium therapy for selected populations and staging PET for all FDG-avid cancers - due COB 21 August 2024 [SEC=OFFICIAL]
Attachments: MSAC Recommendations - PET for common cancers and lutetium for metastatic castrate resistant prostate cancer - for consultation - July 2024.docx

Dear ADIA

The Department of Health and Aged Care is consulting on item descriptions for several new diagnostic imaging item which were recommended by the Medical Services Advisory Committee (MSAC) at their 4-5 April 2024 meeting, following their consideration of the two applications below.

The MSAC Public Summary Documents, which outline the MSAC decision regarding these applications, have now been published and are available online:

- Application 1562 – Streamlining Medicare Benefits Schedule items for PET Project: initial staging and restaging (including treatment response assessment and suspected recurrence) of all FDG-avid cancers
- Application 1686.1 – ^{177}Lutetium PSMA i&t for metastatic castrate resistant prostate cancer

We would be grateful if your organisation could consider the proposed items in the attached document and provide feedback on their utility and any suggested changes.

Your advice on the proposed services will assist with implementation of the items should the Government support their listing.

Please provide your feedback to s47E(d) @health.gov.au by **5pm on 21 August 2024.**

Kind regards,
s22

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

s22

From: DIMSAC
Sent: Tuesday, 9 July 2024 4:05 PM
To: cosa@cancer.org.au
Cc: DIMSAC
Subject: MBS consultation - proposed new items for lutetium therapy for selected populations and staging PET for all FDG-avid cancers - due COB 21 August 2024 [SEC=OFFICIAL]
Attachments: MSAC Recommendations - PET for common cancers and lutetium for metastatic castrate resistant prostate cancer - for consultation - July 2024.docx

Dear Clinical Oncology Society of Australia

The Department of Health and Aged Care is consulting on item descriptions for several new diagnostic imaging item which were recommended by the Medical Services Advisory Committee (MSAC) at their 4-5 April 2024 meeting, following their consideration of the two applications below.

The MSAC Public Summary Documents, which outline the MSAC decision regarding these applications, have now been published and are available online:

- Application 1562 – Streamlining Medicare Benefits Schedule items for PET Project: initial staging and restaging (including treatment response assessment and suspected recurrence) of all FDG-avid cancers
- Application 1686.1 – ^{177}Lutetium PSMA i&t for metastatic castrate resistant prostate cancer

We would be grateful if your organisation could consider the proposed items in the attached document and provide feedback on their utility and any suggested changes.

Your advice on the proposed services will assist with implementation of the items should the Government support their listing.

Please provide your feedback to s47E(d) @health.gov.au by **5pm on 21 August 2024.**

Kind regards,
s22

Diagnostic Imaging Section

Diagnostic Imaging and Pathology Branch | Medicare Benefits and Digital Health Division
Australian Government Department of Health and Aged Care
s47E(d) @health.gov.au
Canberra ACT 2601, Australia

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

s22

From: DIMSAC
Sent: Tuesday, 9 July 2024 4:05 PM
To: cosa@cancer.org.au
Cc: DIMSAC
Subject: MBS consultation - proposed new items for lutetium therapy for selected populations and staging PET for all FDG-avid cancers - due COB 21 August 2024 [SEC=OFFICIAL]
Attachments: MSAC Recommendations - PET for common cancers and lutetium for metastatic castrate resistant prostate cancer - for consultation - July 2024.docx

Dear Clinical Oncology Society of Australia

The Department of Health and Aged Care is consulting on item descriptions for several new diagnostic imaging item which were recommended by the Medical Services Advisory Committee (MSAC) at their 4-5 April 2024 meeting, following their consideration of the two applications below.

The MSAC Public Summary Documents, which outline the MSAC decision regarding these applications, have now been published and are available online:

- Application 1562 – Streamlining Medicare Benefits Schedule items for PET Project: initial staging and restaging (including treatment response assessment and suspected recurrence) of all FDG-avid cancers
- Application 1686.1 – ^{177}Lutetium PSMA i&t for metastatic castrate resistant prostate cancer

We would be grateful if your organisation could consider the proposed items in the attached document and provide feedback on their utility and any suggested changes.

Your advice on the proposed services will assist with implementation of the items should the Government support their listing.

Please provide your feedback to s47E(d) @health.gov.au by **5pm on 21 August 2024.**

Kind regards,
s22

Diagnostic Imaging Section

Diagnostic Imaging and Pathology Branch | Medicare Benefits and Digital Health Division
Australian Government Department of Health and Aged Care
s47E(d) @health.gov.au
Canberra ACT 2601, Australia

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

s22

From: DIMSAC
Sent: Tuesday, 9 July 2024 4:08 PM
To: director@garvan.org.au
Cc: DIMSAC
Subject: MBS consultation - proposed new items for lutetium therapy for selected populations and staging PET for all FDG-avid cancers - due COB 21 August 2024 [SEC=OFFICIAL]
Attachments: MSAC Recommendations - PET for common cancers and lutetium for metastatic castrate resistant prostate cancer - for consultation - July 2024.docx

Dear Garvan Institute

The Department of Health and Aged Care is consulting on item descriptions for several new diagnostic imaging item which were recommended by the Medical Services Advisory Committee (MSAC) at their 4-5 April 2024 meeting, following their consideration of the two applications below.

The MSAC Public Summary Documents, which outline the MSAC decision regarding these applications, have now been published and are available online:

- Application 1562 – Streamlining Medicare Benefits Schedule items for PET Project: initial staging and restaging (including treatment response assessment and suspected recurrence) of all FDG-avid cancers
- Application 1686.1 – ^{177}Lutetium PSMA i&t for metastatic castrate resistant prostate cancer

We would be grateful if your organisation could consider the proposed items in the attached document and provide feedback on their utility and any suggested changes.

Your advice on the proposed services will assist with implementation of the items should the Government support their listing.

Please provide your feedback to s47E(d) @health.gov.au by **5pm on 21 August 2024.**

Kind regards,
s22

Diagnostic Imaging Section

Diagnostic Imaging and Pathology Branch | Medicare Benefits and Digital Health Division
Australian Government Department of Health and Aged Care
s47E(d) @health.gov.au
Canberra ACT 2601, Australia

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

s22

From: DIMSAC
Sent: Tuesday, 9 July 2024 4:06 PM
To: moga@moga.org.au
Cc: DIMSAC
Subject: MBS consultation - proposed new items for lutetium therapy for selected populations and staging PET for all FDG-avid cancers - due COB 21 August 2024 [SEC=OFFICIAL]
Attachments: MSAC Recommendations - PET for common cancers and lutetium for metastatic castrate resistant prostate cancer - for consultation - July 2024.docx

Dear Medical Oncology Group of Australia

The Department of Health and Aged Care is consulting on item descriptions for several new diagnostic imaging item which were recommended by the Medical Services Advisory Committee (MSAC) at their 4-5 April 2024 meeting, following their consideration of the two applications below.

The MSAC Public Summary Documents, which outline the MSAC decision regarding these applications, have now been published and are available online:

- Application 1562 – Streamlining Medicare Benefits Schedule items for PET Project: initial staging and restaging (including treatment response assessment and suspected recurrence) of all FDG-avid cancers
- Application 1686.1 – ^{177}Lutetium PSMA i&t for metastatic castrate resistant prostate cancer

We would be grateful if your organisation could consider the proposed items in the attached document and provide feedback on their utility and any suggested changes.

Your advice on the proposed services will assist with implementation of the items should the Government support their listing.

Please provide your feedback to s47E(d) @health.gov.au by **5pm on 21 August 2024.**

Kind regards,
s22

Diagnostic Imaging Section

Diagnostic Imaging and Pathology Branch | Medicare Benefits and Digital Health Division
Australian Government Department of Health and Aged Care
s47E(d) @health.gov.au
Canberra ACT 2601, Australia

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

s22

From: DIMSAC
Sent: Tuesday, 9 July 2024 4:15 PM
To: s47F @movember.com
Cc: DIMSAC
Subject: MBS consultation - proposed new items for lutetium therapy for selected populations and staging PET for all FDG-avid cancers - due COB 21 August 2024 [SEC=OFFICIAL]
Attachments: MSAC Recommendations - PET for common cancers and lutetium for metastatic castrate resistant prostate cancer - for consultation - July 2024.docx

Dear s47F

The Department of Health and Aged Care is consulting on item descriptions for several new diagnostic imaging item which were recommended by the Medical Services Advisory Committee (MSAC) at their 4-5 April 2024 meeting, following their consideration of the two applications below.

The MSAC Public Summary Documents, which outline the MSAC decision regarding these applications, have now been published and are available online:

- Application 1562 – Streamlining Medicare Benefits Schedule items for PET Project: initial staging and restaging (including treatment response assessment and suspected recurrence) of all FDG-avid cancers
- Application 1686.1 – ^{177}Lutetium PSMA i&t for metastatic castrate resistant prostate cancer

We would be grateful if your organisation could consider the proposed items in the attached document and provide feedback on their utility and any suggested changes.

Your advice on the proposed services will assist with implementation of the items should the Government support their listing.

Please provide your feedback to s47E(d) @health.gov.au by **5pm on 21 August 2024.**

Kind regards,
s22

Diagnostic Imaging Section

Diagnostic Imaging and Pathology Branch | Medicare Benefits and Digital Health Division
Australian Government Department of Health and Aged Care
s47E(d) @health.gov.au
Canberra ACT 2601, Australia

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

s22

From: DIMSAC
Sent: Tuesday, 9 July 2024 4:06 PM
To: pcpa@amaq.com.au
Cc: DIMSAC
Subject: MBS consultation - proposed new items for lutetium therapy for selected populations and staging PET for all FDG-avid cancers - due COB 21 August 2024 [SEC=OFFICIAL]
Attachments: MSAC Recommendations - PET for common cancers and lutetium for metastatic castrate resistant prostate cancer - for consultation - July 2024.docx

Dear Private Cancer Physicians of Australia

The Department of Health and Aged Care is consulting on item descriptions for several new diagnostic imaging item which were recommended by the Medical Services Advisory Committee (MSAC) at their 4-5 April 2024 meeting, following their consideration of the two applications below.

The MSAC Public Summary Documents, which outline the MSAC decision regarding these applications, have now been published and are available online:

- Application 1562 – Streamlining Medicare Benefits Schedule items for PET Project: initial staging and restaging (including treatment response assessment and suspected recurrence) of all FDG-avid cancers
- Application 1686.1 – ^{177}Lutetium PSMA i&t for metastatic castrate resistant prostate cancer

We would be grateful if your organisation could consider the proposed items in the attached document and provide feedback on their utility and any suggested changes.

Your advice on the proposed services will assist with implementation of the items should the Government support their listing.

Please provide your feedback to s47E(d) @health.gov.au by **5pm on 21 August 2024.**

Kind regards,
s22

Diagnostic Imaging Section

Diagnostic Imaging and Pathology Branch | Medicare Benefits and Digital Health Division
Australian Government Department of Health and Aged Care
s47E(d) @health.gov.au
Canberra ACT 2601, Australia

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

s22

From: DIMSAC
Sent: Tuesday, 9 July 2024 4:03 PM
To: s47F @pcfa.org.au; enquiries@pcfa.org.au
Cc: DIMSAC
Subject: MBS consultation - proposed new items for lutetium therapy for selected populations and staging PET for all FDG-avid cancers - due COB 21 August 2024 [SEC=OFFICIAL]
Attachments: MSAC Recommendations - PET for common cancers and lutetium for metastatic castrate resistant prostate cancer - for consultation - July 2024.docx

Dear Prostate Cancer Foundation of Australia

The Department of Health and Aged Care is consulting on item descriptions for several new diagnostic imaging item which were recommended by the Medical Services Advisory Committee (MSAC) at their 4-5 April 2024 meeting, following their consideration of the two applications below.

The MSAC Public Summary Documents, which outline the MSAC decision regarding these applications, have now been published and are available online:

- Application 1562 – Streamlining Medicare Benefits Schedule items for PET Project: initial staging and restaging (including treatment response assessment and suspected recurrence) of all FDG-avid cancers
- Application 1686.1 – ^{177}Lutetium PSMA i&t for metastatic castrate resistant prostate cancer

We would be grateful if your organisation could consider the proposed items in the attached document and provide feedback on their utility and any suggested changes.

Your advice on the proposed services will assist with implementation of the items should the Government support their listing.

Please provide your feedback to s47E(d) @health.gov.au by **5pm on 21 August 2024.**

Kind regards,
s22

Diagnostic Imaging Section

Diagnostic Imaging and Pathology Branch | Medicare Benefits and Digital Health Division
Australian Government Department of Health and Aged Care
s47E(d) @health.gov.au
Canberra ACT 2601, Australia

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

s22

From: DIMSAC
Sent: Tuesday, 9 July 2024 3:57 PM
To: ama@ama.com.au
Cc: DIMSAC
Subject: MBS consultation - proposed new items for lutetium therapy for selected populations and staging PET for all FDG-avid cancers - due COB 21 August 2024 [SEC=OFFICIAL]
Attachments: MSAC Recommendations - PET for common cancers and lutetium for metastatic castrate resistant prostate cancer - for consultation - July 2024.docx

Dear AMA

The Department of Health and Aged Care is consulting on item descriptions for several new diagnostic imaging item which were recommended by the Medical Services Advisory Committee (MSAC) at their 4-5 April 2024 meeting, following their consideration of the two applications below.

The MSAC Public Summary Documents, which outline the MSAC decision regarding these applications, have now been published and are available online:

- Application 1562 – Streamlining Medicare Benefits Schedule items for PET Project: initial staging and restaging (including treatment response assessment and suspected recurrence) of all FDG-avid cancers
- Application 1686.1 – ^{177}Lutetium PSMA i&t for metastatic castrate resistant prostate cancer

We would be grateful if your organisation could consider the proposed items in the attached document and provide feedback on their utility and any suggested changes.

Your advice on the proposed services will assist with implementation of the items should the Government support their listing.

Please provide your feedback to s47E(d) @health.gov.au by **5pm on 21 August 2024.**

Kind regards,
s22

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

s22

From: DIMSAC
Sent: Tuesday, 9 July 2024 4:01 PM
To: secretariat@anzsnm.org.au
Cc: DIMSAC
Subject: MBS consultation - proposed new items for lutetium therapy for selected populations and staging PET for all FDG-avid cancers - due COB 21 August 2024 [SEC=OFFICIAL]
Attachments: MSAC Recommendations - PET for common cancers and lutetium for metastatic castrate resistant prostate cancer - for consultation - July 2024.docx

Dear Australia and New Zealand Society of Nuclear Medicine

The Department of Health and Aged Care is consulting on item descriptions for several new diagnostic imaging item which were recommended by the Medical Services Advisory Committee (MSAC) at their 4-5 April 2024 meeting, following their consideration of the two applications below.

The MSAC Public Summary Documents, which outline the MSAC decision regarding these applications, have now been published and are available online:

- Application 1562 – Streamlining Medicare Benefits Schedule items for PET Project: initial staging and restaging (including treatment response assessment and suspected recurrence) of all FDG-avid cancers
- Application 1686.1 – ^{177}Lutetium PSMA i&t for metastatic castrate resistant prostate cancer

We would be grateful if your organisation could consider the proposed items in the attached document and provide feedback on their utility and any suggested changes.

Your advice on the proposed services will assist with implementation of the items should the Government support their listing.

Please provide your feedback to s47E(d) @health.gov.au by **5pm on 21 August 2024.**

Kind regards,
s22

Diagnostic Imaging Section

Diagnostic Imaging and Pathology Branch | Medicare Benefits and Digital Health Division
Australian Government Department of Health and Aged Care
s47E(d) @health.gov.au
Canberra ACT 2601, Australia

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

s22

From: DIMSAC
Sent: Tuesday, 9 July 2024 3:58 PM
To: 'info@asmirt.org'
Cc: DIMSAC
Subject: MBS consultation - proposed new items for lutetium therapy for selected populations and staging PET for all FDG-avid cancers - due COB 21 August 2024 [SEC=OFFICIAL]
Attachments: MSAC Recommendations - PET for common cancers and lutetium for metastatic castrate resistant prostate cancer - for consultation - July 2024.docx

Dear ASMIRT

The Department of Health and Aged Care is consulting on item descriptions for several new diagnostic imaging item which were recommended by the Medical Services Advisory Committee (MSAC) at their 4-5 April 2024 meeting, following their consideration of the two applications below.

The MSAC Public Summary Documents, which outline the MSAC decision regarding these applications, have now been published and are available online:

- Application 1562 – Streamlining Medicare Benefits Schedule items for PET Project: initial staging and restaging (including treatment response assessment and suspected recurrence) of all FDG-avid cancers
- Application 1686.1 – ^{177}Lutetium PSMA i&t for metastatic castrate resistant prostate cancer

We would be grateful if your organisation could consider the proposed items in the attached document and provide feedback on their utility and any suggested changes.

Your advice on the proposed services will assist with implementation of the items should the Government support their listing.

Please provide your feedback to s47E(d) @health.gov.au by **5pm on 21 August 2024.**

Kind regards,
s22

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

s22

From: DIMSAC
Sent: Tuesday, 9 July 2024 4:28 PM
To: BID Policy Advice
Cc: DIMSAC; s47F
Subject: FYI ONLY - MBS consultation - proposed new items for lutetium therapy for selected populations and staging PET for all FDG-avid cancers [SEC=OFFICIAL]
Attachments: MSAC Recommendations - PET for common cancers and lutetium for metastatic castrate resistant prostate cancer - for consultation - July 2024.docx

Good afternoon

We've begun consulting on the item descriptors for two new items for Lutetium treatment for patients with metastatic castrate resistant prostate cancer (including a PET scan for eligibility for Lutetium treatment), and amending the PET for rare cancer items to be available for patients with any FDG-avid cancer. These items were recommended for public funding by MSAC at their April 2024 meeting (see Application 1562 – Streamlining Medicare Benefits Schedule items for PET Project: initial staging and restaging (including treatment response assessment and suspected recurrence) of all FDG-avid cancers, and Application 1686.1 – ^{177}Lutetium PSMA i&t for metastatic castrate resistant prostate cancer for more info).

Note this MSAC recommendation has not yet been considered by Government. We are anticipating a 1 July 2025 start date for the new item, however this is dependent on a decision of Government in the context of the budget.

Could you please distribute to other relevant areas as required, including PHI, PRS and AskMBS.

Should you require further information or have any input to this draft item, please don't hesitate to get in touch.

Thanks,
s22

Diagnostic Imaging Section

Diagnostic Imaging and Pathology Branch | Medicare Benefits and Digital Health Division
Australian Government Department of Health and Aged Care
s47E(d) @health.gov.au
Canberra ACT 2601, Australia

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

s22

From: DIMSAC
Sent: Tuesday, 9 July 2024 4:04 PM
To: info@cancer.org.au
Cc: DIMSAC
Subject: MBS consultation - proposed new items for lutetium therapy for selected populations and staging PET for all FDG-avid cancers - due COB 21 August 2024 [SEC=OFFICIAL]
Attachments: MSAC Recommendations - PET for common cancers and lutetium for metastatic castrate resistant prostate cancer - for consultation - July 2024.docx

Dear Cancer Council Australia

The Department of Health and Aged Care is consulting on item descriptions for several new diagnostic imaging item which were recommended by the Medical Services Advisory Committee (MSAC) at their 4-5 April 2024 meeting, following their consideration of the two applications below.

The MSAC Public Summary Documents, which outline the MSAC decision regarding these applications, have now been published and are available online:

- Application 1562 – Streamlining Medicare Benefits Schedule items for PET Project: initial staging and restaging (including treatment response assessment and suspected recurrence) of all FDG-avid cancers
- Application 1686.1 – ^{177}Lutetium PSMA i&t for metastatic castrate resistant prostate cancer

We would be grateful if your organisation could consider the proposed items in the attached document and provide feedback on their utility and any suggested changes.

Your advice on the proposed services will assist with implementation of the items should the Government support their listing.

Please provide your feedback to s47E(d) @health.gov.au by **5pm on 21 August 2024.**

Kind regards,
s22

Diagnostic Imaging Section

Diagnostic Imaging and Pathology Branch | Medicare Benefits and Digital Health Division
Australian Government Department of Health and Aged Care
s47E(d) @health.gov.au
Canberra ACT 2601, Australia

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

s22

From: BID Policy Advice
Sent: Monday, 5 August 2024 5:12 PM
To: DIMSAC; BID Policy Advice
Cc: s47F
Subject: RE: FYI ONLY - MBS consultation - proposed new items for lutetium therapy for selected populations and staging PET for all FDG-avid cancers [SEC=OFFICIAL]
Attachments: BID Comments - MSAC Recommendations - PET for common cancers and lutetium for metastatic castrate .docx

Good afternoon s22

Please see attached BID's comments regarding the proposed item descriptors for the new items for Lutetium treatment and the item to be amended for a PET for rare cancer items.

We have provided comment on the utility of the descriptor and possible further considerations.

Please let me know if you have any further queries.

Kind regards,

s47F

Compliance Officer
Behavioural Economics and Engagement Section | Compliance Risk and Provider Engagement Branch
Benefits Integrity Division | Health Resourcing Group

Australian Government, Department of Health and Aged Care
E s47F @health.gov.au
Location: 595 Collins St, Melbourne 3000
PO Box 9848, Canberra ACT 2601, Australia

This email comes to you from Wurundjeri Country

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

From: DIMSAC
Sent: Tuesday, July 9, 2024 4:28 PM
To: BID Policy Advice
Cc: DIMSAC ; s47F
Subject: FYI ONLY - MBS consultation - proposed new items for lutetium therapy for selected populations and staging PET for all FDG-avid cancers [SEC=OFFICIAL]

Good afternoon

We've begun consulting on the item descriptors for two new items for Lutetium treatment for patients with metastatic castrate resistant prostate cancer (including a PET scan for eligibility for Lutetium treatment), and amending the PET for rare cancer items to be available for patients with any FDG-avid cancer. These items were recommended for public funding by MSAC at their April 2024 meeting (see Application 1562 – Streamlining Medicare Benefits Schedule items for PET Project: initial staging and restaging (including treatment response assessment and suspected recurrence) of all FDG-avid cancers, and Application 1686.1 – ^{177}Lutetium PSMA i&t for metastatic castrate resistant prostate cancer for more info).

Note this MSAC recommendation has not yet been considered by Government. We are anticipating a 1 July 2025 start date for the new item, however this is dependent on a decision of Government in the context of the budget.

Could you please distribute to other relevant areas as required, including PHI, PRS and AskMBS.

Should you require further information or have any input to this draft item, please don't hesitate to get in touch.

Thanks,
s22

Diagnostic Imaging Section

Diagnostic Imaging and Pathology Branch | Medicare Benefits and Digital Health Division
Australian Government Department of Health and Aged Care
s47E(d) @health.gov.au
Canberra ACT 2601, Australia

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Australian Government

Department of Health and Aged Care

New Medicare Benefits Scheme (MBS) items for consultation – theranostic and diagnostic imaging services

Guidance for your consultation response:
Please read the document below and in the spaces provided include your comments and suggested amendments (where applicable). Your advice regarding all components of a proposed service is sought, such as:

- the utility of the item description in clinical practice as a requestor and/or provider of this proposed service,
- the appropriateness of the requesting and provider requirements, and
- the suitability of the proposed schedule fee (if an alternative fee is suggested, please validate this suggestion with a justification for why this fee is more appropriate, and where possible, provide a breakdown of costs).

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Application 1686.1: ^{177}Lutetium PSMA i&t for metastatic castrate resistant prostate cancer

New items for the treatment of progressive or symptomatic metastatic castrate resistant prostate cancer in patients who have received at least one androgen receptor signalling inhibitor as well as at least one line of chemotherapy (docetaxel +/- cabazitaxel).

- **Draft Items 1-2 and explanatory note:** draft therapeutic intervention ^{177}Lutetium (Lu) prostate specific membrane antigen (PSMA) for initial and continuing treatment, for which treatment eligibility is determined by
- **Draft Item 3:** A diagnostic whole body PSMA positron emission tomography/computerised tomography (PET/CT) scan.

Draft Item 1: Lu PSMA initial treatment item

Category 3 – Therapeutic procedures T3 – Therapeutic Nuclear Medicine
Item 16019 Administration of Lutetium 177 PSMA followed 24 hours later by whole body Lu-PSMA single-photon emission computed tomography (SPECT) for treatment of a patient with metastatic castrate resistant prostate cancer, who is PSMA-positive as determined by PSMA PET (defined as SUVmax >15 at a single site of disease and SUVmax >10 at all sites of measurable disease) after progressive disease has developed while on at least one taxane chemotherapy and at least one androgen receptor signalling inhibitor. Eligible to claim once per cycle, to a maximum of 2 cycles in the initial treatment phase. Fee: $8,000.00 75% and 85% benefits will apply *Note: Item number is indicative, subject to final approval, and the fee is equivalent to a 1 July 2024 fee.*

s47C

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Draft Item 2: Lu PSMA continuing treatment item

Category 3 – Therapeutic procedures T3 – Therapeutic Nuclear Medicine
Item 16020 Administration of Lutetium 177 PSMA followed 24 hours later by whole body Lu-PSMA single-photon emission computed tomography (SPECT) for treatment of a patient with metastatic castrate resistant prostate cancer, if: • a service to which item 16019 has been provided; and • the patient must not have developed disease progression while receiving Lutetium 177 PSMA for this condition. Eligible to claim once per cycle, to a maximum of 4 cycles in the continuing treatment phase. Fee: $8,000.00 75% and 85% benefits will apply *Note: Item number is indicative, subject to final approval, and the fee is equivalent to a 1 July 2024 fee.*
s47C [redacted]

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Draft Explanatory Note for Lu PSMA continuing treatment item (YYYY):

Item 16020 – Lutetium PSMA continuing treatment item for the treatment of progressive or symptomatic metastatic castrate resistant prostate cancer (mCRPC) For Item 16020 disease progression is defined as: • a rise in PSA of > 2 ng/mL confirmed by two tests a minimum of two weeks apart, and/or • evidence of new soft tissue metastases on diagnostic computed tomography as per the Response Evaluation Criteria in Solid Tumours (RECIST) criteria, as published by the European Organisation for Research and Treatment of Cancer and available online at: RECIST (eortc.org)
s47C [redacted]

Draft Item 3: diagnostic whole body PSMA PET/CT scan to determine eligibility for Lu PSMA therapy.

Category 5 – Diagnostic Imaging Services Group I4 – Nuclear Medicine Imaging Subgroup 2 – PET
Item 61528 Whole body prostate specific membrane antigen (PSMA) positron emission tomography study, performed for the assessment of suitability for Lutetium 177 PSMA therapy in a patient with metastatic castrate resistant prostate cancer after progressive disease has developed while on at least one taxane chemotherapy and at least one androgen receptor signalling inhibitor. (R) (Anaes) Fee: $1,300.00 75% and 85% benefits will apply *Note: Item number is indicative, subject to final approval, and the fee is equivalent to a 1 July 2024 fee.*
s47C

This Document Has Been Released Under the Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Application 1562: fluorodeoxyglucose (FDG) PET for initial staging and restaging of all typically FDG-avid cancers

Proposed amendments to existing MBS Item 61612 and new Item 61614 (to be implemented for restaging of rare cancers on 1 November 2024), to extend coverage of these services to include initial staging and restaging (including treatment response assessment and recurrence) for all typically FDG-avid cancers.

- **Amendment to Item 61612 and explanatory note:** whole body FDG PET study for the initial staging of a typically FDG-avid cancer for a patient who is considered suitable for active therapy if there is at least a 10% likelihood that the PET study result will inform a significant change in management for the patient.
- **Amendment to Item 61614:** whole body FDG PET study, following initial therapy, for the evaluation of suspected residual, metastatic or recurrent cancer for a patient who is undergoing or is suitable for active therapy of a typically FDG-avid cancer.

Amendment to Item 61612 - PET for initial staging of all typically FDG-avid cancers

Note: red underlined text shows proposed text to be amended in the item description. Black strikethrough text shows proposed deletions to the current item description.

s47C

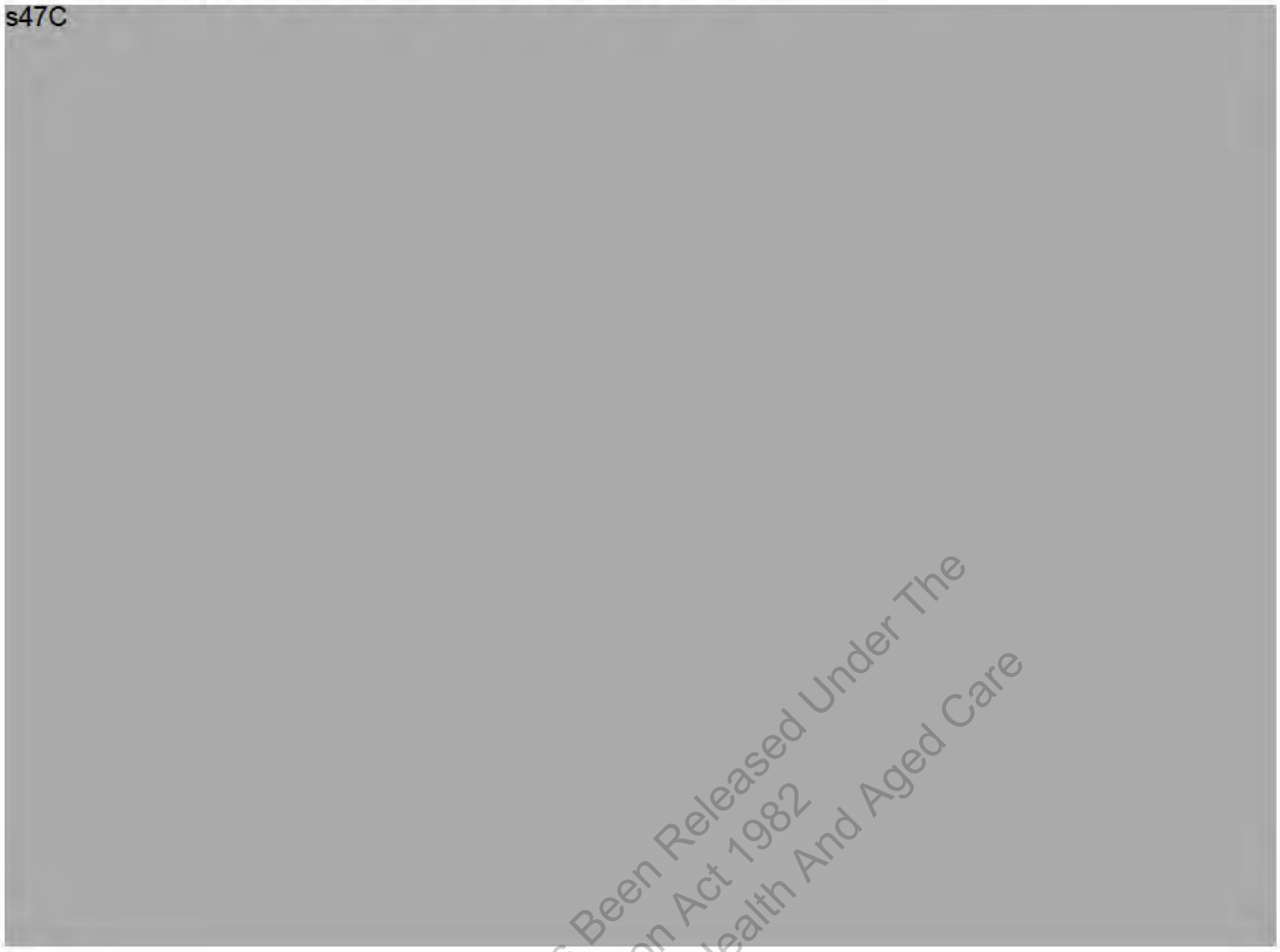
This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Amendment to Item 61614 - PET for initial staging of all typically FDG-avid cancers

Note: Item 61614 will be implemented for rare and uncommon cancers from 1 November 2024, with the addotopma; expansion to include all FDG-avid cancers subject to Government consideration.

Red underlined text shows proposed text to be amended in the item description. Black strikethrough text shows proposed deletions to current item description.

s47C



This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

s22

From: s47F @movember.com>
Sent: Monday, 26 August 2024 4:47 PM
To: DIMSAC
Subject: Re: MBS consultation - proposed new items for lutetium therapy for selected populations and staging PET for all FDG-avid cancers - due COB 21 August 2024 [SEC=OFFICIAL]

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Hi s22
I wanted to follow up to let you know that Movember and the Advanced Prostate Cancer Access Alliance (APCAA) that we coordinate are very supportive of the 2 proposed MBS items. Movember does not have anything additional to add to the proposal, which is why we did not submit a formal response last week. Many of the clinical experts and specialist organisations within our APCAA submitted their own responses to the MBS items on specific considerations they had.
We appreciate the inclusion in this consultation and hope that you will continue to consider us for future requests.
Kind regards,
s47F

s47F
Global Director, Prostate Cancer
T 1300 GROW MO s47F
movember.com

CHANGING THE FACE OF MEN'S HEALTH

Movember acknowledges the Traditional Custodians of Country throughout Australia and their connection to land, sea and community. We pay our respects to their Elders past and present, and extend that respect to all Aboriginal and Torres Strait Islander peoples today.

[v001]

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

s22 [redacted]

s22

This Document Has Been Released Under The
Freedom Of Information Act 1982
By The Department Of Health And Aged Care

s22

From: s47F
Sent: Friday, 16 August 2024 3:43 PM
To: DIMSAC
Cc: s47F
Subject: RE: MBS consultation - proposed new items for lutetium therapy for selected populations and staging PET for all FDG-avid cancers - due COB 21 August 2024 [SEC=OFFICIAL]
Attachments: MSAC Recommendations - PET for common cancers and lutetium for metastatic castrate resistant prostate cancer - for consultation.pdf

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Dear s47F

Please find attached USANZ completed MSAC recommendations for PET for common cancers and lutetium for metastatic castrate resistant prostate cancer document.

Kind regards

s47F
Governance Support Officer
s47F @usanz.org.au

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

s22

s22

This Document Has Been Released Under The
Freedom Of Information Act 1982
By The Department Of Health And Aged Care

Australian Government

Department of Health and Aged Care

New Medicare Benefits Scheme (MBS) items for consultation – theranostic and diagnostic imaging services

Guidance for your consultation response:

Please read the document below and in the spaces provided include your comments and suggested amendments (where applicable). Your advice regarding all components of a proposed service is sought, such as:

- the utility of the item description in clinical practice as a requestor and/or provider of this proposed service,
- the appropriateness of the requesting and provider requirements, and
- the suitability of the proposed schedule fee (if an alternative fee is suggested, please validate this suggestion with a justification for why this fee is more appropriate, and where possible, provide a breakdown of costs).

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

General Feedback

s47C, s47G(1)(b)

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Application 1686.1: ^{177}Lutetium PSMA i&t for metastatic castrate resistant prostate cancer

New items for the treatment of progressive or symptomatic metastatic castrate resistant prostate cancer in patients who have received at least one androgen receptor signalling inhibitor as well as at least one line of chemotherapy (docetaxel +/- cabazitaxel).

- **Draft Items 1-2 and explanatory note:** draft therapeutic intervention ^{177}Lutetium (Lu) prostate specific membrane antigen (PSMA) for initial and continuing treatment, for which treatment eligibility is determined by
- **Draft Item 3:** A diagnostic whole body PSMA positron emission tomography/computerised tomography (PET/CT) scan.

Draft Item 1: Lu PSMA initial treatment item

Category 3 – Therapeutic procedures T3 – Therapeutic Nuclear Medicine
Item 16019 Administration of Lutetium 177 PSMA followed 24 hours later by whole body Lu-PSMA single-photon emission computed tomography (SPECT) for treatment of a patient with metastatic castrate resistant prostate cancer, who is PSMA-positive as determined by PSMA PET (defined as SUVmax >15 at a single site of disease and SUVmax >10 at all sites of measurable disease) after progressive disease has developed while on at least one taxane chemotherapy and at least one androgen receptor signalling inhibitor. Eligible to claim once per cycle, to a maximum of 2 cycles in the initial treatment phase. Fee: $8,000.00 75% and 85% benefits will apply *Note: Item number is indicative, subject to final approval, and the fee is equivalent to a 1 July 2024 fee.*
Feedback: s47C, s47G(1)(b) [redacted]

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Draft Item 2: Lu PSMA continuing treatment item

Category 3 – Therapeutic procedures T3 – Therapeutic Nuclear Medicine
Item 16020 Administration of Lutetium 177 PSMA followed 24 hours later by whole body Lu-PSMA single-photon emission computed tomography (SPECT) for treatment of a patient with metastatic castrate resistant prostate cancer, if: • a service to which item 16019 has been provided; and • the patient must not have developed disease progression while receiving Lutetium 177 PSMA for this condition. Eligible to claim once per cycle, to a maximum of 4 cycles in the continuing treatment phase. Fee: $8,000.00 75% and 85% benefits will apply *Note: Item number is indicative, subject to final approval, and the fee is equivalent to a 1 July 2024 fee.*

s47C, s47G(1)(b) [redacted]

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Draft Explanatory Note for Lu PSMA continuing treatment item (YYYY):

Item 16020 – Lutetium PSMA continuing treatment item for the treatment of progressive or symptomatic metastatic castrate resistant prostate cancer (mCRPC) For Item 16020 disease progression is defined as: • a rise in PSA of > 2 ng/mL confirmed by two tests a minimum of two weeks apart, and/or • evidence of new soft tissue metastases on diagnostic computed tomography as per the Response Evaluation Criteria in Solid Tumours (RECIST) criteria, as published by the European Organisation for Research and Treatment of Cancer and available online at: RECIST (eortc.org)
Feedback: s47C, s47G(1)(b) [redacted]

Draft Item 3: diagnostic whole body PSMA PET/CT scan to determine eligibility for Lu PSMA therapy.

Category 5 – Diagnostic Imaging Services Group I4 – Nuclear Medicine Imaging Subgroup 2 – PET
Item 61528 Whole body prostate specific membrane antigen (PSMA) positron emission tomography study, performed for the assessment of suitability for Lutetium 177 PSMA therapy in a patient with metastatic castrate resistant prostate cancer after progressive disease has developed while on at least one taxane chemotherapy and at least one androgen receptor signalling inhibitor. (R) (Anaes) Fee: $1,300.00 75% and 85% benefits will apply *Note: Item number is indicative, subject to final approval, and the fee is equivalent to a 1 July 2024 fee.*
Feedback: s47C, s47G(1)(b)

This Document Has Been Released Under the Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Application 1562: fluorodeoxyglucose (FDG) PET for initial staging and restaging of all typically FDG-avid cancers

Proposed amendments to existing MBS Item 61612 and new Item 61614 (to be implemented for restaging of rare cancers on 1 November 2024), to extend coverage of these services to include initial staging and restaging (including treatment response assessment and recurrence) for all typically FDG-avid cancers.

- **Amendment to Item 61612 and explanatory note:** whole body FDG PET study for the initial staging of a typically FDG-avid cancer for a patient who is considered suitable for active therapy if there is at least a 10% likelihood that the PET study result will inform a significant change in management for the patient.
- **Amendment to Item 61614:** whole body FDG PET study, following initial therapy, for the evaluation of suspected residual, metastatic or recurrent cancer for a patient who is undergoing or is suitable for active therapy of a typically FDG-avid cancer.

Amendment to Item 61612 - PET for initial staging of all typically FDG-avid cancers

Note: red underlined text shows proposed text to be amended in the item description. Black strikethrough text shows proposed deletions to the current item description.

s47C, s47G(1)(b)

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

-7-

Amendment to Item 61614 - PET for initial staging of all typically FDG-avid cancers

Note: Item 61614 will be implemented for rare and uncommon cancers from 1 November 2024, with the addotopma; expansion to include all FDG-avid cancers subject to Government consideration. Red underlined text shows proposed text to be amended in the item description. Black strikethrough text shows proposed deletions to current item description.

s47C, s47G(1)(b)

[redacted]

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

s22

From: s47F @austin.org.au>
Sent: Wednesday, 21 August 2024 3:44 PM
To: DIMSAC
Cc: s47F
Subject: MSAC Recommendations - FDG PET and LuPSMA for Prostate Cancer
Attachments: AANMS_MSAC Recommendations - PET for common cancers and lutetium for metastatic castrate resistant prostate cancer - for consultation - July 2024 _FINAL.docx

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.
To Whom It May Concern

Please find attached submission from AANMS regarding the Consultation feedback on the Recommendation due today.

Thank your for the opportunity to have input. We look forward to working with you on this.

Please don't hesitate to reach out for further clarification if needed.

Best wishes,
s47F

Immediate Past President
AANMS

CONFIDENTIALITY NOTICE: This email and any files transmitted with it are confidential and are to be used solely by the individual or entity to whom it is addressed. If you are not the intended recipient and have received this email in error, please be aware that any disclosure, copying or distribution of the information it contains; or taking any action in reliance on the contents of this information, is strictly prohibited and may be unlawful. Please notify us by return email that you have received the email and delete all copies in your system.

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

The Royal Australian and New Zealand College of Radiologists®

Diagnostic Imaging and Pathology Branch
Medicare Benefits and Digital Health Division
Australian Government Department of Health and Aged Care

Via email: s47E(d) @health.gov.au

27 August 2024

RANZCR response to MSAC Application 1686.1 – 177Lutetium PSMA i&t for metastatic castrate resistant prostate cancer

The Royal Australian and New Zealand College of Radiologists (RANZCR) is committed to improving health outcomes for all, by educating and supporting clinical radiologists and radiation oncologists. RANZCR is dedicated to setting standards, professional training, assessment and accreditation, and advocating access to quality care in both professions to create healthier communities.

RANZCR creates a positive impact by driving change, focusing on the professional development of its members and advancing best practice health policy and advocacy, to enable better patient outcomes. RANZCR members are critical to health services: radiation oncology is a vital component in the treatment of cancer; clinical radiology is central to the diagnosis and treatment of disease and injury.

Thank you for the opportunity to provide feedback with regards to the MSAC Application 1686.1 – 177Lutetium PSMA i&t for metastatic castrate resistant prostate cancer.

RANZCR is supportive of government funding for 177Lutetium PSMA i&t for metastatic castrate resistant prostate cancer in principle and agrees that the use of 177Lutetium PSMA (Lu PSMA) therapy to treat patients is clinically beneficial. However, we have concerns that there may be significant financial barriers to patient access. In consultation with our key committees and clinicians, RANZCR would like to draw the attention of the Department of Health and Aged Care (DoHAC) to the below:

- RANZCR is supportive of the proposed wording in the item descriptors.
- We recommend the draft explanatory note be amended to include bone progression (i.e., evidence of new soft tissue and/or bone progression metastases) to ensure patients are not inadvertently excluded in accessing this item.
- We strongly recommend that the patients receiving these services are managed via a multidisciplinary team (MDT) and that the requesting doctor is a specialist in the field (i.e., an oncological surgeon, physician, or oncologist (medical oncology or radiation)).
- The proposed fee for MBS item 61528 for positron emission tomography (PET) is appropriate.
- We have significant concerns about the proposed fees for the treatment items (MBS items 16019 and 16020) as these are inadequate to cover the cost of delivering the service. This is particularly critical for services performed outside of large tertiary hospitals with an on-site cyclotron (which are limited in Australia), inadvertently creating serious patient access issues across Australia.
- We recommend the fees for the treatment items be revised to ensure there is an equity of access, particularly for non-metropolitan patients.
- RANZCR strongly supports the item descriptor aligning with the MSAC recommendation of not specifying the specialist recognition required for the provider of the service. To ensure there is an equity of access for patients, doctors across a variety of clinical backgrounds should be eligible to deliver this service, dependent on their upskilling requirements.
- There are multiple medical specialty training programs which deliver some of the competencies related to the delivery of theranostics. Practitioners within these specialties

This Document Has Been Released Under The FOI Act 1982 By The Department Of Health And Aged Care

would be able to upskill in various areas depending on their core training to enable them to safely practice theranostics.

- RANZCR refers DoHAC to a high-level document it has developed which outlines the competencies required to deliver theranostics and will assist in the guidance of professional development of practitioners.[1]
- RANZCR supports the MBS explanatory notes broadly referring to a 'specialist with appropriate competency to deliver the service' but encourages DoHAC to not identify the specialty required.

RANZCR welcomes the opportunity to work with the government to ensure there are no inadvertent adverse patient outcomes during this process. RANZCR advocates best practice health policy to enable better patient outcomes and looks forward to further collaboration on all and any other related health matters.

For queries or further information, please contact s47F Policy Officer, on s47F s47F or email at s47F @ranzcr.edu.au or s47F Policy Officer, on s47F s47F or email s47F @ranzcr.edu.au.

Yours sincerely

s47F

Dean, Faculty of Clinical Radiology
The Royal Australian and New Zealand College of Radiologists

Dean, Faculty of Radiation Oncology
The Royal Australian and New Zealand College of Radiologists

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

[1] The Royal Australian and New Zealand College of Radiologists. *Competencies for Professional Development in Theranostics*. Available from: https://www.ranzcr.com/college/document-library/competencies-for-professional-development-in-theranostics

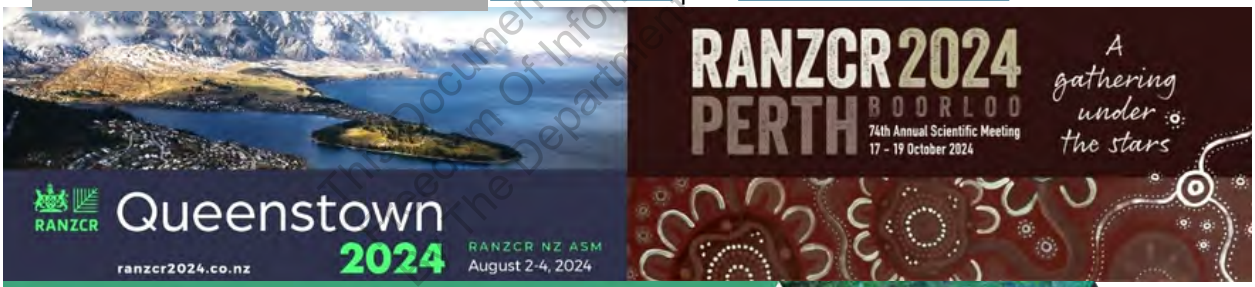
s22

From: s47F @ranzcr.edu.au>
Sent: Tuesday, 27 August 2024 8:23 AM
To: DIMSAC
Cc: s47F
Subject: Re: RANZCR response to proposed MBS items for the provision of 177Lutetium PSMA i&t for metastatic castrate resistant prostate cancer
Attachments: 20240827 RANZCR response to MSAC application 1686.1 - 177Lutetium PSMA.pdf

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Good morning,
Thank you for the opportunity for RANZCR to provide feedback to the Department of Health and Aged Care on the proposed item descriptors and explanatory notes for MSAC application 1686.1- 177 Lutetium PSMA i&t for metastatic castrate resistant prostate cancer.
Please find attached RANZCR's response. If you have any questions, please don't hesitate to reach out. Thanks again for the opportunity.
Kind regards,

s47F
Have I been of assistance to you today? Click here to respond.
s47F **| Policy Officer | Policy and Advocacy Unit**
The Royal Australian and New Zealand College of Radiologists
Level 9, 51 Druitt Street, Sydney 2000 NSW
T: s47F anzcr.edu.au | W: www.ranzcr.edu.au



This email and any attachments are confidential, privileged or private and intended solely for the use of the individual or the entity to whom they are addressed. If you have received this email in error, please notify the sender immediately and delete the email. The Royal Australian and New Zealand College of Radiologists disclaims liability for the contents of private emails.

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Australian Government

Department of Health and Aged Care

New Medicare Benefits Scheme (MBS) items for consultation – theranostic and diagnostic imaging services

Guidance for your consultation response:
Please read the document below and in the spaces provided include your comments and suggested amendments (where applicable). Your advice regarding all components of a proposed service is sought, such as:

- the utility of the item description in clinical practice as a requestor and/or provider of this proposed service,
- the appropriateness of the requesting and provider requirements, and
- the suitability of the proposed schedule fee (if an alternative fee is suggested, please validate this suggestion with a justification for why this fee is more appropriate, and where possible, provide a breakdown of costs).

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Application 1686.1: ^{177}Lutetium PSMA i&t for metastatic castrate resistant prostate cancer

New items for the treatment of progressive or symptomatic metastatic castrate resistant prostate cancer in patients who have received at least one androgen receptor signalling inhibitor as well as at least one line of chemotherapy (docetaxel +/- cabazitaxel).

- **Draft Items 1-2 and explanatory note:** draft therapeutic intervention ^{177}Lutetium (Lu) prostate specific membrane antigen (PSMA) for initial and continuing treatment, for which treatment eligibility is determined by
- **Draft Item 3:** A diagnostic whole body PSMA positron emission tomography/computerised tomography (PET/CT) scan.

Draft Item 1: Lu PSMA initial treatment item

Category 3 – Therapeutic procedures T3 – Therapeutic Nuclear Medicine
Item 16019 Administration of Lutetium 177 PSMA followed 24 hours later by whole body Lu-PSMA single-photon emission computed tomography (SPECT) for treatment of a patient with metastatic castrate resistant prostate cancer, who is PSMA-positive as determined by PSMA PET (defined as SUVmax >15 at a single site of disease and SUVmax >10 at all sites of measurable disease) after progressive disease has developed while on at least one taxane chemotherapy and at least one androgen receptor signalling inhibitor. Eligible to claim once per cycle, to a maximum of 2 cycles in the initial treatment phase. Fee: $8,000.00 75% and 85% benefits will apply *Note: Item number is indicative, subject to final approval, and the fee is equivalent to a 1 July 2024 fee.*
Feedback:

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Draft Item 2: Lu PSMA continuing treatment item

Category 3 – Therapeutic procedures T3 – Therapeutic Nuclear Medicine
Item 16020 Administration of Lutetium 177 PSMA followed 24 hours later by whole body Lu-PSMA single-photon emission computed tomography (SPECT) for treatment of a patient with metastatic castrate resistant prostate cancer, if: • a service to which item 16019 has been provided; and • the patient must not have developed disease progression while receiving Lutetium 177 PSMA for this condition. Eligible to claim once per cycle, to a maximum of 4 cycles in the continuing treatment phase. Fee: $8,000.00 75% and 85% benefits will apply *Note: Item number is indicative, subject to final approval, and the fee is equivalent to a 1 July 2024 fee.*
Feedback: s47C, s47G(1)(b) [redacted]

Draft Explanatory Note for Lu PSMA continuing treatment item (YYYY):

Item 16020 – Lutetium PSMA continuing treatment item for the treatment of progressive or symptomatic metastatic castrate resistant prostate cancer (mCRPC) For Item 16020 disease progression is defined as: • a rise in PSA of > 2 ng/mL confirmed by two tests a minimum of two weeks apart, and/or • evidence of new soft tissue metastases on diagnostic computed tomography as per the Response Evaluation Criteria in Solid Tumours (RECIST) criteria, as published by the European Organisation for Research and Treatment of Cancer and available online at: RECIST (eortc.org)
Feedback: s47C, s47G(1)(b) [redacted]

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Draft Item 3: diagnostic whole body PSMA PET/CT scan to determine eligibility for Lu PSMA therapy.

Category 5 – Diagnostic Imaging Services Group I4 – Nuclear Medicine Imaging Subgroup 2 – PET
Item 61528 Whole body prostate specific membrane antigen (PSMA) positron emission tomography study, performed for the assessment of suitability for Lutetium 177 PSMA therapy in a patient with metastatic castrate resistant prostate cancer after progressive disease has developed while on at least one taxane chemotherapy and at least one androgen receptor signalling inhibitor. (R) (Anaes) Fee: $1,300.00 75% and 85% benefits will apply *Note: Item number is indicative, subject to final approval, and the fee is equivalent to a 1 July 2024 fee.*
Feedback:

Application 1562: fluorodeoxyglucose (FDG) PET for initial staging and restaging of all typically FDG-avid cancers

Proposed amendments to existing MBS Item 61612 and new Item 61614 (to be implemented for restaging of rare cancers on 1 November 2024), to extend coverage of these services to include initial staging and restaging (including treatment response assessment and recurrence) for all typically FDG-avid cancers.

- **Amendment to Item 61612 and explanatory note:** whole body FDG PET study for the initial staging of a typically FDG-avid cancer for a patient who is considered suitable for active therapy if there is at least a 10% likelihood that the PET study result will inform a significant change in management for the patient.
- **Amendment to Item 61614:** whole body FDG PET study, following initial therapy, for the evaluation of suspected residual, metastatic or recurrent cancer for a patient who is undergoing or is suitable for active therapy of a typically FDG-avid cancer.

Amendment to Item 61612 - PET for initial staging of all typically FDG-avid cancers

Note: red underlined text shows proposed text to be amended in the item description. Black strikethrough text shows proposed deletions to the current item description.

s47C, s47G(1)(b)

[redacted]

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Amendment to Item 61614 - PET for initial staging of all typically FDG-avid cancers

Note: Item 61614 will be implemented for rare and uncommon cancers from 1 November 2024, with the addotopma; expansion to include all FDG-avid cancers subject to Government consideration. Red underlined text shows proposed text to be amended in the item description. Black strikethrough text shows proposed deletions to current item description.

s47C

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

s22

From: s47F
Sent: Wednesday, 21 August 2024 10:22 AM
To: DIMSAC
Cc: s22 ; WARNER, Mary
Subject: RE: MBS consultation - proposed new items for lutetium therapy for selected populations and staging PET for all FDG-avid cancers - due COB 21 August 2024 [SEC=OFFICIAL]

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Good morning,
Thank you for the opportunity to provide feedback on proposed item descriptors for Lutetium PSMA therapy for metastatic castrate resistant prostate cancer.
ADIA is the peak industry body representing private and not-for-profit radiology practices in Australia, with our member practices providing a comprehensive range of services in more than 750 locations across the country. Several ADIA members are already providing privately-funded theranostics, including Lutetium PSMA therapy, in community and private hospital settings throughout metropolitan and regional Australia.

The MBS fee is insufficient to make Lutetium PSMA therapy viable outside tertiary public hospital settings

MSAC is recommending an MBS fee of $8,000, providing a rebate of $7,901.30. This is inadequate. In feedback to applications 1686 and 1686.1, ADIA repeatedly advised MSAC that at least $10,000 per cycle is necessary to cover the cost of providing a ^{177}Lutetium PSMA i&t service, as the cost of the radiopharmaceutical for private providers is typically $8,000 or more per dose.
A small number of public facilities can access the radiopharmaceutical at a lower cost, but these arrangements are outside the commercial market and not available to private providers.
Setting the Medicare rebate well below the cost of provision would force private providers to charge substantial gaps, and due to anachronistic Medicare billing arrangements still in place, patients would pay the full cost (likely $10,000 or more) upfront, then claim the Medicare rebate. This is a substantial and unfair financial burden on men with prostate cancer.
The likely outcome is a distortion of the theranostics market, with Lutetium PSMA therapy restricted mostly to public facilities with favourable procurement arrangements. The service is well-suited to provision by clinicians in community settings in suburban and regional locations, but this potential will be limited by the inadequate fee.

The Department should clarify the legal right to use LuPSMA i&t in Australia

MSAC's advice to the Minister states that it recommends creation of new Medicare items "*On the basis of the current evidence and on the premise that providers will have a legal right to use ^{177}LuPSMA i&t in Australia if the application is approved…*".

s47D, s47G(1)(a)

To allow providers to plan ahead of Medicare listing, we encourage the Department to clarify the legal position of ^{177}LuPSMA i&t in Australia as soon as possible.

Response assessment should allow PSMA PET as well as SPECT

ADIA suggests that the item descriptor allows the theranostics practitioner to choose the most appropriate imaging tool response assessment. This could be SPECT, or alternatively PSMA PET to provide better access for patients and a more comprehensive clinical assessment of response.

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Response assessment data is still evolving with no long-term international data to support SPECT alone to be used as a response assessment. In contrast, there is data on PSMA PET criteria (such as RECIP) which has attempted to provide validated system of response assessment using PSMA PET.

Response assessment is usually a combination of factors and not just one imaging modality. Restricting response assessment to SPECT alone risks restriction of the service to facilities with SPECT capability, where theranostics facilities may have a combination of imaging modalities available at hand.

In addition, restricting response assessment to SPECT will erect a barrier to future developments in PET, not just for Lutetium PSMA therapy but for other theranostics services.

Regards,

Chris

s47F | **CEO**

Australian Diagnostic Imaging Association

71B Grosvenor Street South Yarra VIC 3141

s47F

W www.adia.asn.au

s22

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

s22

From: s22
Sent: Tuesday, 6 August 2024 5:07 PM
To: DIMSAC; s22
Subject: RE: FYI ONLY - MBS consultation - proposed new items for lutetium therapy for selected populations and staging PET for all FDG-avid cancers [SEC=OFFICIAL]

Hi s22

The suggestion for 24 hours later seems sensible. The wording would need to be changed within both 16019 and 16020.

I agree with your plan for no pre requisite items and not identifying the speciality groups as per BID's recommendation for the reason you outlined.

I don't have a problem with the explanatory note recommendation.

Don't think you are missing anything else.

s22

s22 *[Her/She]*
Medical Adviser
MBS Policy and Specialist Programs

Medicare Benefits and Digital Health Division | Health Resourcing Group
Australian Government Department of Health and Aged Care
T: 02 6289 s22 | E: s22 @health.gov.au

This email comes to you from Ngunnawal Country
Location: Sirius 4.North
PO Box 9848, Canberra ACT 2601, Australia
The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

From: DIMSAC
Sent: Tuesday, August 6, 2024 9:18 AM
To: s22
Cc: DIMSAC
Subject: RE: FYI ONLY - MBS consultation - proposed new items for lutetium therapy for selected populations and staging PET for all FDG-avid cancers [SEC=OFFICIAL]

Hi s22 – there's a question in the BID feedback on Lutetium and the timeframe of the SPECT after administration which I'd appreciate your views on, it seems straightforward enough however there may be a clinical aspect which means their feedback can't apply. Let me know what you think!

Thanks,
s22

From: BID Policy Advice s47E(d) @Health.gov.au>
Sent: Monday, August 5, 2024 5:12 PM
To: DIMSAC s47E(d) @health.gov.au>; BID Policy Advice s47E(d) @Health.gov.au>
Cc: s22 @health.gov.au>
Subject: RE: FYI ONLY - MBS consultation - proposed new items for lutetium therapy for selected populations and staging PET for all FDG-avid cancers [SEC=OFFICIAL]

Good afternoon s22

Please see attached BID's comments regarding the proposed item descriptors for the new items for Lutetium treatment and the item to be amended for a PET for rare cancer items.

We have provided comment on the utility of the descriptor and possible further considerations.

Please let me know if you have any further queries.

Kind regards,

s22

Compliance Officer
Behavioural Economics and Engagement Section | Compliance Risk and Provider Engagement Branch
Benefits Integrity Division | Health Resourcing Group

Australian Government, Department of Health and Aged Care
E: s22 @health.gov.au
Location: 595 Collins St, Melbourne 3000
PO Box 9848, Canberra ACT 2601, Australia

This email comes to you from Wurundjeri Country

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

s22

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

s22

This Document Has Been Released Under The
Freedom Of Information Act 1982
By The Department Of Health And Aged Care

s22

From: s22
Sent: Monday, 23 September 2024 4:27 PM
To: s22
Cc:
Subject: RE: Lutetium item descriptions - for your consideration following consultation [SEC=OFFICIAL]

Chat with s22 Decided to:

- Leave item descriptions the same except for increasing to 36 hours the time period for SPECT.
- Update note to include DI options for assessment of response (e.g. progression of disease). See drafts below.

From: s22
Sent: Monday, September 23, 2024 1:05 PM
To s22
Cc
Subject: RE: Lutetium item descriptions - for your consideration following consultation [SEC=OFFICIAL]

Hi s22

I appreciate the time line, but it may be worth trying to clarify the ADIA comment intent. Suggesting this as based on the clinical information that went through MSAC I don't think the proposed drafting changes are correct. More than happy to discuss, however I'll try to explain my reasoning.

My understanding of the clinical pathway:

- PSMA PET to assess baseline suitability
- Treatment day
- SPECT immediately after the treatment to assess uptake at tumour sites
- PSMA PET after cycle (or potentially a couple of cycles) to assess progress and reassess ongoing suitability for treatment. This is not done at the point of treatment, rather just prior to commencing a new cycle.

So the issue I see with the draft is that the PSMA PET wouldn't be within 36 hours, like the SPECT. I'm not sure that we would consider it part of the 'care' in the same way SPECT is either. Based on this understanding I don't think changing the wording to something like 'any imaging done within the treatment cycle' is necessarily right. However if this is incorrect, then my drafting below is wrong and you need to remove the timeframes and include wording that captures all imaging.

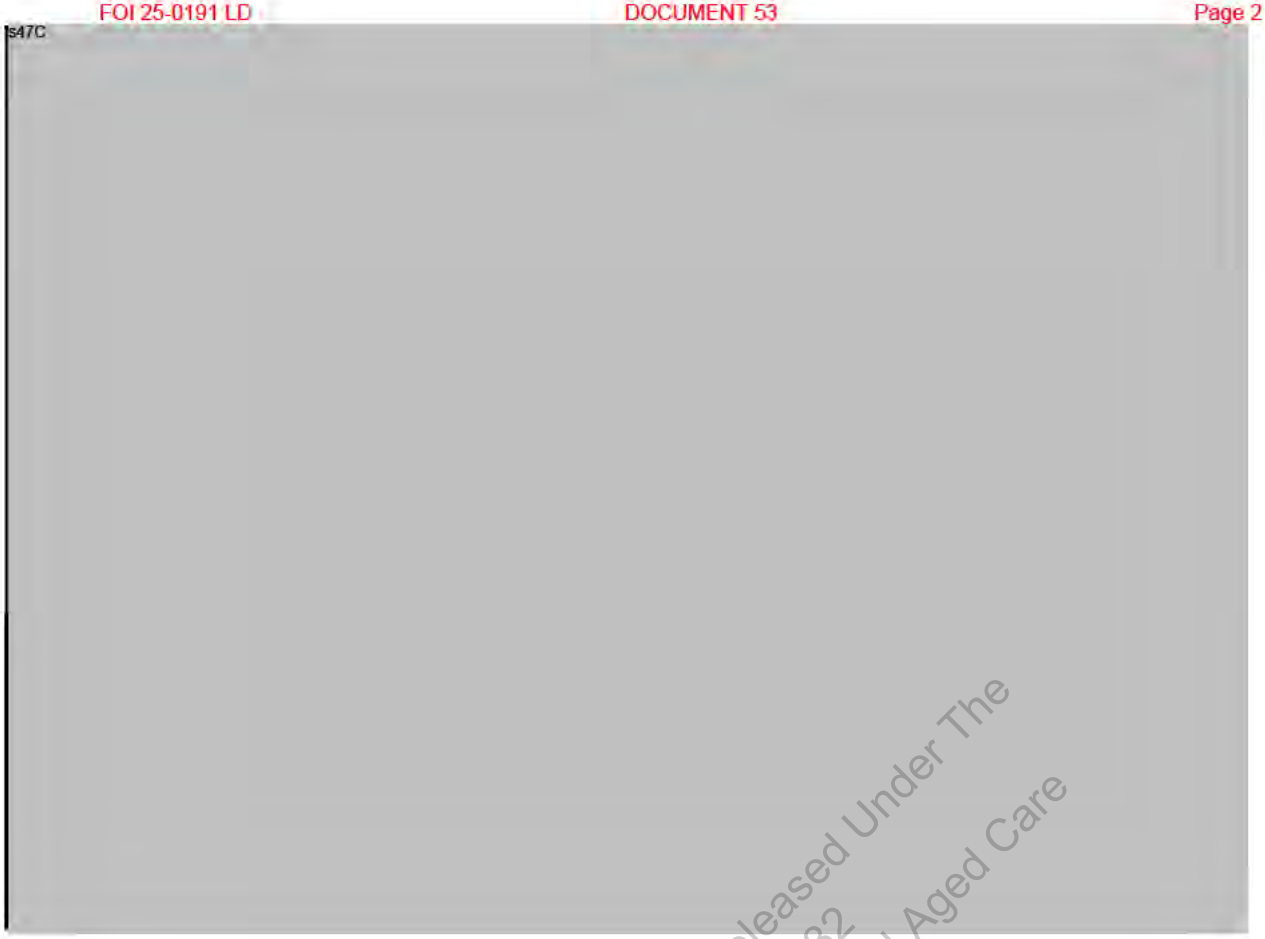
Based on my understanding I did think there are two issues with the feedback:

- Not all sites may have SPECT, so this needs to read potentially as 'optional' in the treatment.
- It needs to be clear that ongoing treatment decisions can be made based on PSMA PET +/- SPECT +/- clinical response to treatment.

However I don't think PSMA PET needs to be in the item descriptor beyond the initial access information. This would leave item numbers and an explanatory note that looked something like the following:

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

s47C



s47C

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

s47C [redacted]

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Let me know if you want to talk about this one.

s22 [redacted] (He/Him)
Medical Adviser
MBS Policy and Specialist Programs

Medicare Benefits and Digital Health Division | Health Resourcing Group
Australian Government Department of Health and Aged Care
T: 02 6289 s22 | E: s22 [redacted] @health.gov.au

This email comes to you from Ngunnawal Country
Location: Sirius 4.North
PO Box 9848, Canberra ACT 2601, Australia
The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: s22 [redacted] @health.gov.au>
Sent: Monday, September 23, 2024 12:00 PM
To: s22 [redacted] @Health.gov.au>
Cc: s22 [redacted] @health.gov.au>
Subject: Lutetium item descriptions - for your consideration following consultation [SEC=OFFICIAL]

Hi s22 [redacted]

From the consultation responses for the proposed Lu PSMA items for mCRPC, I've compiled the following amendments (in red text and strike through). The changes are from the following

responses below. Do these make sense and are they appropriate/do you agree? Particularly around the follow up scan and including the option for providers to pick the modality between SPECT and PSMA PET to check for response following lutetium administration.

We need to have the initial drafting instructions for MIRS (formerly SPRU) by Wednesday, fyi

Thanks!

s22

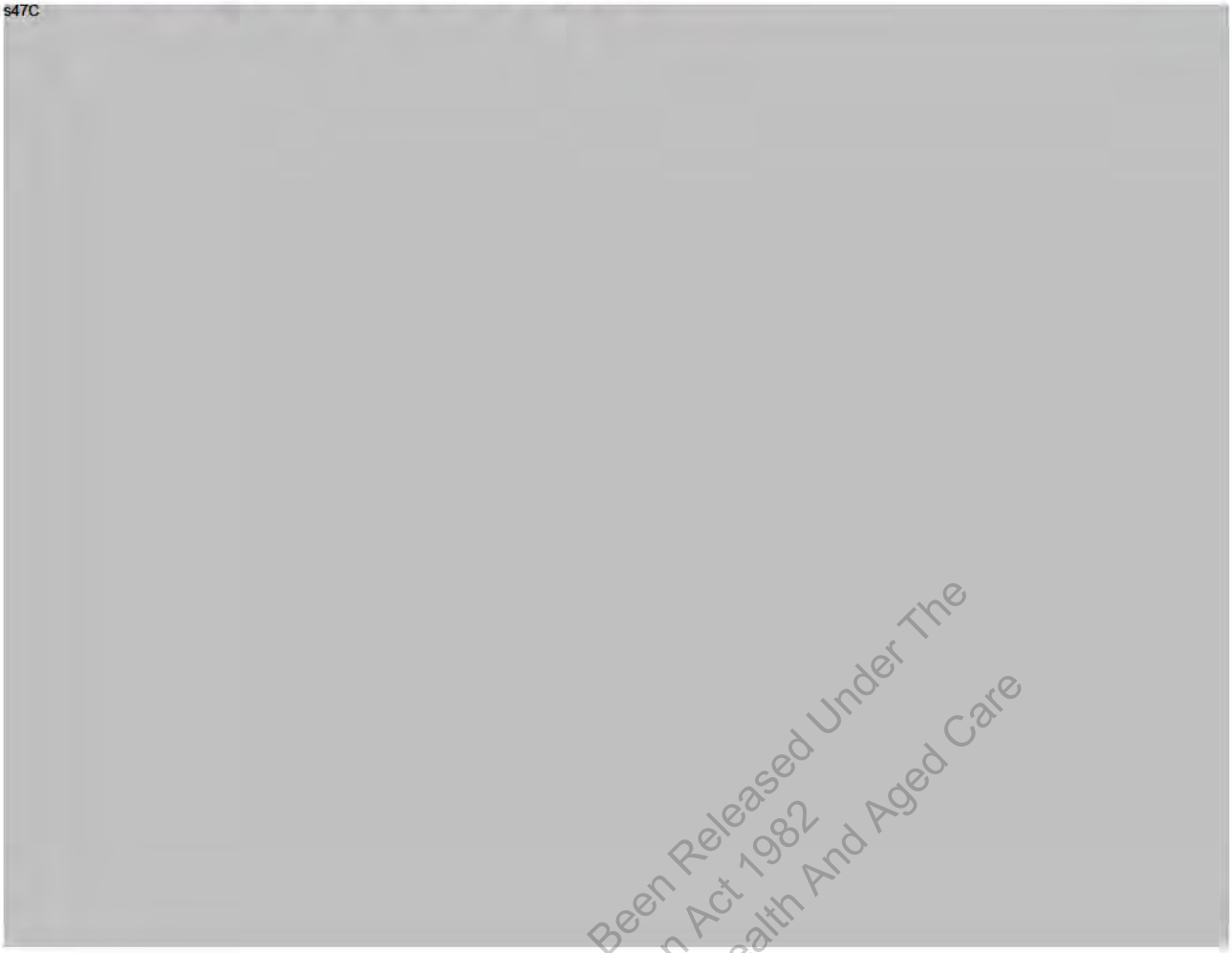
Consultation input:

s47C, s47G(1)(b)

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Draft Item 1: Lu PSMA initial treatment item

s47C



This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Draft Item 2: Lu PSMA continuing treatment item

s47C

[redacted]

[redacted]

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

s22

From: DIMSAC
Sent: Tuesday, 6 August 2024 9:18 AM
To: s22
Cc: DIMSAC
Subject: RE: FYI ONLY - MBS consultation - proposed new items for lutetium therapy for selected populations and staging PET for all FDG-avid cancers [SEC=OFFICIAL]
Attachments: BID Comments - MSAC Recommendations - PET for common cancers and lutetium for metastatic castrate - KR comments.docx

Hi s22 – there's a question in the BID feedback on Lutetium and the timeframe of the SPECT after administration which I'd appreciate your views on, it seems straightforward enough however there may be a clinical aspect which means their feedback can't apply. Let me know what you think!

Thanks,
s22

From: BID Policy Advice s47E(d) @Health.gov.au>
Sent: Monday, August 5, 2024 5:12 PM
To: DIMSAC s47E(d) @health.gov.au>; BID Policy Advice s47E(d) @Health.gov.au>
Cc: s22 @health.gov.au>
Subject: RE: FYI ONLY - MBS consultation - proposed new items for lutetium therapy for selected populations and staging PET for all FDG-avid cancers [SEC=OFFICIAL]

Good afternoon s22

Please see attached BID's comments regarding the proposed item descriptors for the new items for Lutetium treatment and the item to be amended for a PET for rare cancer items.

We have provided comment on the utility of the descriptor and possible further considerations.

Please let me know if you have any further queries.

Kind regards,

s22

Compliance Officer
Behavioural Economics and Engagement Section | Compliance Risk and Provider Engagement Branch
Benefits Integrity Division | Health Resourcing Group

Australian Government, Department of Health and Aged Care
E: s22 @health.gov.au
Location: 595 Collins St, Melbourne 3000
PO Box 9848, Canberra ACT 2601, Australia

This email comes to you from Wurundjeri Country

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

s22

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

s22

This Document Has Been Released Under The
Freedom Of Information Act 1982
By The Department Of Health And Aged Care

Australian Government
Department of Health and Aged Care

New Medicare Benefits Scheme (MBS) items for consultation – theranostic and diagnostic imaging services

Guidance for your consultation response:
Please read the document below and in the spaces provided include your comments and suggested amendments (where applicable). Your advice regarding all components of a proposed service is sought, such as:

- the utility of the item description in clinical practice as a requestor and/or provider of this proposed service,
- the appropriateness of the requesting and provider requirements, and
- the suitability of the proposed schedule fee (if an alternative fee is suggested, please validate this suggestion with a justification for why this fee is more appropriate, and where possible, provide a breakdown of costs).

Application 1686.1: ^{177}Lutetium PSMA i&t for metastatic castrate resistant prostate cancer

New items for the treatment of progressive or symptomatic metastatic castrate resistant prostate cancer in patients who have received at least one androgen receptor signalling inhibitor as well as at least one line of chemotherapy (docetaxel +/- cabazitaxel).

- **Draft Items 1-2 and explanatory note:** draft therapeutic intervention ^{177}Lutetium (Lu) prostate specific membrane antigen (PSMA) for initial and continuing treatment, for which treatment eligibility is determined by
- **Draft Item 3:** A diagnostic whole body PSMA positron emission tomography/computerised tomography (PET/CT) scan.

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

s47C

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Draft Item 2: Lu PSMA continuing treatment item

s47C

s47C

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Draft Item 3: diagnostic whole body PSMA PET/CT scan to determine eligibility for Lu PSMA therapy.

Category 5 – Diagnostic Imaging Services Group I4 – Nuclear Medicine Imaging Subgroup 2 – PET
Item 61528 Whole body prostate specific membrane antigen (PSMA) positron emission tomography study, performed for the assessment of suitability for Lutetium 177 PSMA therapy in a patient with metastatic castrate resistant prostate cancer after progressive disease has developed while on at least one taxane chemotherapy and at least one androgen receptor signalling inhibitor. (R) (Anaes) Fee: $1,300.00 75% and 85% benefits will apply *Note: Item number is indicative, subject to final approval, and the fee is equivalent to a 1 July 2024 fee.*
Feedback: Nil comments.

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Application 1562: fluorodeoxyglucose (FDG) PET for initial staging and restaging of all typically FDG-avid cancers

Proposed amendments to existing MBS Item 61612 and new Item 61614 (to be implemented for restaging of rare cancers on 1 November 2024), to extend coverage of these services to include initial staging and restaging (including treatment response assessment and recurrence) for all typically FDG-avid cancers.

- **Amendment to Item 61612 and explanatory note:** whole body FDG PET study for the initial staging of a typically FDG-avid cancer for a patient who is considered suitable for active therapy if there is at least a 10% likelihood that the PET study result will inform a significant change in management for the patient.
- **Amendment to Item 61614:** whole body FDG PET study, following initial therapy, for the evaluation of suspected residual, metastatic or recurrent cancer for a patient who is undergoing or is suitable for active therapy of a typically FDG-avid cancer.

Amendment to Item 61612 - PET for initial staging of all typically FDG-avid cancers

Note: red underlined text shows proposed text to be amended in the item description. Black strikethrough text shows proposed deletions to the current item description.

s47C

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Red underlined text shows proposed text to be amended in the item description. Black strikethrough text shows proposed deletions to current item description.

s47C

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Regulation drafting instructions –GMST & DIST & 3C Determinations

This document includes drafting instructions for all changes to the Health Insurance (Diagnostic Imaging Services Table) Regulations (No. 2) 2020 (DIST), Health Insurance (General Medical Services Table) Regulations 2021 and relevant 3C Determinations commencing 1 July 2025.

SUBJECT TITLES AND POLICY AUTHORITY

Change Number	Subject	Policy Authority
s22 [redacted]		
4	**Change 4: 177LUTETIUM PSMA I&T FOR ELIGIBLE PATIENTS WITH METASTATIC** CASTRATE RESISTANT PROSTATE CANCER	Pending authority in the 2024-25 Mid-Year Economic and Fiscal Outlook.
s22 [redacted]		

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

s22

SENSITIVITIES

There are no sensitivities identified with any of the changes, the exception being ^{177}Lutetium PSMA i&t for eligible patients with metastatic castrate resistant prostate cancer. This is why we have requested a 3C determination that will provide flexibility to adjust quickly to potential market conditions if required.

s22

CONSULTATION WITH PEAK BODIES

Consultation with the following organisations was undertaken:

- Australasian Association of Nuclear Medicine Specialists (AANMS)
- Australian and New Zealand Society of Nuclear Medicine (ANZSNM)
- Australian Diagnostic Imaging Association (ADIA)
- Australian Society of Medical Imaging and Radiation Therapy (ASMIRT)
- Rural Alliance in Nuclear Scintigraphy (RAINS)
- The Royal Australian and New Zealand College of Radiologists (RANZCR)

For some changes, additional consultation took place. These organisations will be listed in the 'details' section for the relevant change.

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

CONSULTATION WITH SERVICES AUSTRALIA (SA)

Services Australia has been consulted about the changes as required. External costing requests have been agreed, and business requirements will be provided in accordance with SA timeframes.

CONSULTATION WITH PRIVATE HEALTH INSURANCE BRANCH AND COMPLIANCE

Private Health Insurance Branch and Benefits Integrity Division will be consulted on the changes.

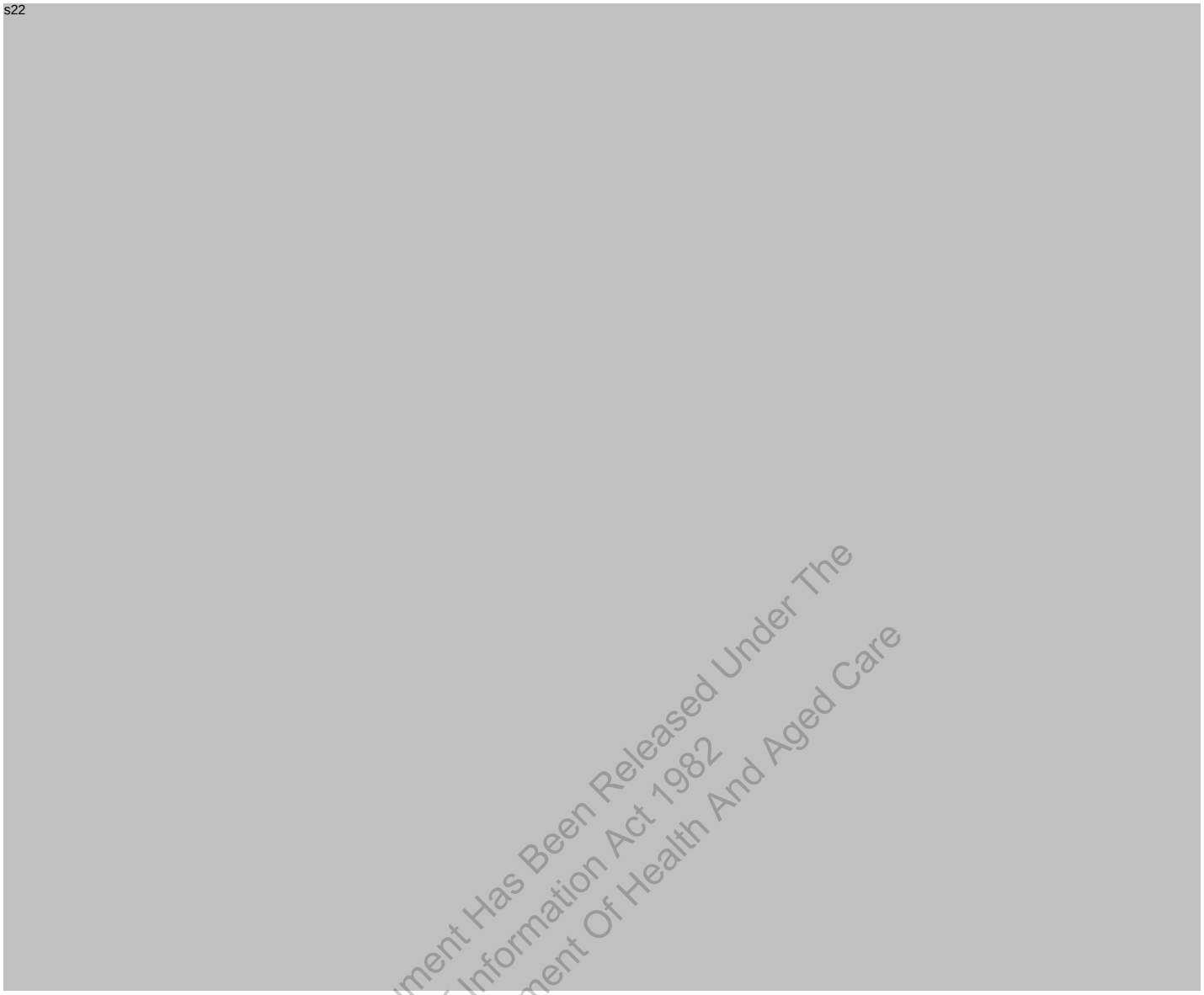
CONSULTATION WITH MOMS ADMINISTRATOR

Relevant explanatory notes will be amended to reflect changes. In addition, web material will be updated to reflect the changes as required.

s22

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

s22



This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

s22

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

s22

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

s22

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Change 4: ^{177}LUTETIUM PSMA I&T FOR ELIGIBLE PATIENTS WITH METASTATIC CASTRATE RESISTANT PROSTATE CANCER

DETAILS OF THE CHANGE

From 1 July 2025, two therapeutic nuclear medicine MBS items for the treatment of progressive or symptomatic metastatic castrate resistant prostate cancer, where prior treatment has failed, will be introduced.

It is proposed that Therapeutic nuclear medicine Items 16050 and 16055 be listed in the General Medical Services Table (GMST) via a 3C Determination. This will provide flexibility to respond to potential changes to this service given that there are potential supply issues with the radiopharmaceutical used for this treatment.

Eligibility for which will be determined by a new diagnostic imaging test, whole-body prostate specific membrane antigen (PSMA) PET item 61528 which will be listed in the Diagnostic Imaging Services Table (DIST).

For Lutetium PSMA Items 16050 and 16055, all usual regulations for Category 3 Therapeutic Procedures, Group T3 Therapeutic Nuclear Medicine will apply.

For PSMA PET Item 61528, patients must be referred by a specialist or consultant physician and the service must be provided by a nuclear medicine specialist who meets the eligibility requirements of the DIST. All usual regulations for the provision of PET services will apply.

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

CLINICAL RECOMMENDATION

The MSAC supported funding for these services in April 2024. This change will create three new MBS items:

- Item 61528 – Whole body PSMA PET study
- Item 16050 – Lutetium 177PSMA treatment (initial treatment)
- Item 16055 – Lutetium 177PSMA treatment (continuing treatment)

The MSAC public summary document for this application (1686.1) is available at msac.gov.au.

PROPOSED NEW ITEM DESCRIPTOR - DIST

New items	Category 5 – Diagnostic Imaging Services Group I4 – Nuclear Medicine Imaging Subgroup 2 – PET
61528	Whole body prostate specific membrane antigen (PSMA) positron emission tomography (PET) study, performed for the assessment of suitability for Lutetium 177 PSMA therapy in a patient with metastatic castrate resistant prostate cancer after progressive disease has developed while on at least one taxane chemotherapy and at least one androgen receptor signalling inhibitor. (R) (Anaes) Fee: $1,300.00 Benefit: 75% & 85% Extended Medicare Safety Net Cap (if applicable): N//A Greatest Permissible Gap will apply to out of hospital services

PROPOSED NEW ITEM DESCRIPTORS – GMST via 3C Determination

To facilitate the introduction of two new items into group T3 it is suggested that subgroups now be created as the following:

- 'Subgroup 1 - Administration of Nuclear Medicine' and move existing items 16003 to 16018 into this subgroup. This change would take place in the GMST.
- 'Subgroup 2 – Theranostics' for the new items 16050 and 16055. This will be visualised in the 3C Determination.

This Document Has Been Released Under the Freedom Of Information Act 1982 By The Department Of Health And Aged Care

New items	Category 3 - Therapeutic Procedures GroupT3 -Therapeutic Nuclear Medicine Subgroup 2 – Theranostics
16050	Administration of Lutetium 177 PSMA, followed within 36 hours by whole body Lu-PSMA single-photon emission computed tomography (SPECT), for treatment of a patient with metastatic castrate resistant prostate cancer, who is PSMA-positive as determined by PSMA PET defined as SUVmax >15 at a single site of disease and SUVmax >10 at all sites of measurable disease, after progressive disease has developed while on at least one taxane chemotherapy and at least one androgen receptor signalling inhibitor. Eligible to claim once per cycle up to a maximum of 2 cycles in the initial treatment phase. Fee: $8,000.00 Benefit: 75% & 85% Extended Medicare Safety Net Cap (if applicable): N/A Greatest Permissible Gap will apply to out of hospital services

New items	Category 3 - Therapeutic Procedures GroupT3 -Therapeutic Nuclear Medicine Subgroup 2 – Theranostics
16055	Administration of Lutetium 177 PSMA, followed within 36 hours by whole body Lu-PSMA single-photon emission computed tomography (SPECT), for treatment of a patient with metastatic castrate resistant prostate cancer, if: • a service to which item 16019 applies has been provided; and • the patient must not have developed disease progression while receiving Lutetium 177 PSMA for this condition. Eligible to claim once per cycle, to a maximum of 4 cycles in the continuing treatment phase. Fee: $8,000.00 Benefit: 75% & 85% Extended Medicare Safety Net Cap (if applicable): N/A Greatest Permissible Gap will apply to out of hospital services

Rules of Interpretation

An Explanatory Note will provide information about disease progression for Item 16055 (consultation on this note is in progress). The current note (in draft) is as follows:

Item 16055 should not be claimed if disease progression has occurred while receiving Lutetium 177 PSMA for metastatic castrate resistant prostate cancer.

Response assessment can be made utilising diagnostic imaging modalities including, but not limited to, PSMA PET or Lu-PSMA single-photon emission computed tomography (SPECT), and/or other clinically relevant markers. For Item 16055, disease progression is defined as:

- a rise in PSA of >2ng/mL confirmed by two tests a minimum of two weeks apart, and/or
- evidence of new soft tissue or bone metastases on diagnostic imaging computed tomography as per established guidelines (such as the Response Evaluation Criteria in Solid Tumours (RECIST) criteria, as published by the European Organisation for Research and Treatment of Cancer available online at: www.eortc.org, or the Response Evaluation Criteria in PSMA-Imaging (RECIP) Criteria, available online at www.recip-criteria.com,

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

ADDITIONAL CONSULTATION

In addition to the organisations listed previously, further consultation was undertaken with the following organisations:

- Australian College of Rural and Remote Medicine (ACRRM)
- Australian Medical Association (AMA)
- Prostate Cancer Foundation of Australia
- Cancer Council Australia
- Clinical Oncology Society of Australia (COSA)
- Medical Oncology Group of Australia (MOGA)
- Private Cancer Physicians of Australia

- Urological Society of Australian and New Zealand (USANZ)
- Australian Genomic Cancer Medicine Centre (Garvan Institute)
- Consumer Health Forum (CHF)
- Royal Australasian College of Physicians (RACP)
- Royal Australasian College of Surgeons (RACS)
- Royal Australian College of General Practitioners (RACGP)
- Movember

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

s22

This Document Has Been Released Under The
Freedom Of Information Act 1982
By The Department Of Health And Aged Care

s22

This Document Has Been Released Under The
Freedom Of Information Act 1982
By The Department Of Health And Aged Care

s22

This Document Has Been Released Under The
Freedom Of Information Act 1982
By The Department Of Health And Aged Care

s22

This Document Has Been Released Under The
Freedom Of Information Act 1982
By The Department Of Health And Aged Care

s22 [redacted]

CLINICAL RECOMMENDATION

N/A – administrative change to incorporate the 3C Determination into the DIST.

Program area contact officer for any queries: s22 [redacted]

Director contact details: s22 [redacted], (02) 5162 s22 [redacted]

Assistant Secretary clearance officer: s22 [redacted], delegate to the Assistant Secretary (Diagnostic Imaging and Pathology Branch) approved this on 1 October 2024.

Queries: Please contact s47E(d) [redacted]@health.gov.au . If you have any queries about this template or the regulatory process.

Email: Completed regulation change templates should be sent to s47E(d) [redacted]@health.gov.au, s22 [redacted]@health.gov.au, s22 [redacted]@health.gov.au, s22 [redacted]@health.gov.au, s22 [redacted]@health.gov.au, s22 [redacted]@health.gov.au and s22 [redacted]@health.gov.au.

Cabinet policy authority documents should be sent to s22 [redacted].Health.gov.au, s22 [redacted].Health.gov.au and s22 [redacted].Health.gov.au.

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

s22

From: s22
Sent: Wednesday, 4 December 2024 3:44 PM
To: s22
Cc:
Subject: FW: FOR ACTION (by COB Friday 4 October): DIs for 1 July 2025 MBS legislative changes [SEC=OFFICIAL]
Attachments: Drafting Instructions 1 July 2025 - Diagnostic Imaging Section.docx; DRAFTING INSTRUCTIONS for 1 July 2025 - DI only.docx

Hello 😊

FYI this was the original email, but please make any changes in the share point version.

Thank you!

s22

s22 (She/Her)
Policy Officer – Diagnostic Imaging Section
Diagnostic Imaging and Pathology Branch
Medicare Benefits and Digital Health Division | Health Resourcing Group
Australian Government Department of Health and Aged Care
E: s22 @health.gov.au
Location: 595 Collins Street, Melbourne
GPO Box 9848, Melbourne VIC 3001, Australia

Work days: Full time

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

From: s22 @health.gov.au>
Sent: Wednesday, 4 December 2024 3:04 PM
To: s22 @Health.gov.au>; s22 @health.gov.au>; s22 @Health.gov.au>; s22 @health.gov.au>; s22 @Health.gov.au>
Cc: s22 @Health.gov.au>; s22 @Health.gov.au>; s22 @Health.gov.au>; s22 @health.gov.au>; MBD Regulations s47E(d) @health.gov.au>
Subject: FW: FOR ACTION (by COB Friday 4 October): DIs for 1 July 2025 MBS legislative changes [SEC=OFFICIAL]

Hi all,

Please find attached the diagnostic imaging component of the compiled 1 July 2025 instructions.

Can I please get you to review your relevant parts and provide changes and comments by COB tomorrow so I can progress it to s47F Can you please track any changes so I incorporate them in my working version.

s22

Give me a call if you have any questions.

Cheers

s22 [redacted]

From: s22 [redacted] @Health.gov.au>
Sent: Tuesday, 1 October 2024 3:32 PM
To: MBD Regulations s47E(d) [redacted] @health.gov.au>
Cc: s22 [redacted] @health.gov.au>; s22 [redacted] @Health.gov.au>; s22 [redacted] @health.gov.au>; s22 [redacted] @health.gov.au>
Subject: RE: FOR ACTION (by COB Friday 4 October): DIs for 1 July 2025 MBS legislative changes [SEC=OFFICIAL]

Hi team

Please find attached the 1 July 2025 drafting instructions from the Diagnostic Imaging Section.

Thank you
s22 [redacted]

s22 [redacted] (She/Her)
Policy Officer – Diagnostic Imaging Section
Diagnostic Imaging and Pathology Branch

Medicare Benefits and Digital Health Division | Health Resourcing Group
Australian Government Department of Health and Aged Care
E: s22 [redacted] @health.gov.au
Location: 595 Collins Street, Melbourne
GPO Box 9848, Melbourne VIC 3001, Australia

Work days: Full time

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

---

From: MBD Regulations s47E(d) [redacted] @health.gov.au>
Sent: Thursday, September 19, 2024 11:49 AM
To: s22 [redacted] @health.gov.au>; s22 [redacted] @health.gov.au>; s22 [redacted] @health.gov.au>; s22 [redacted] @Health.gov.au>
Cc: s22 [redacted] @health.gov.au>; s22 [redacted] @Health.gov.au>; s22 [redacted] @health.gov.au>; s22 [redacted] @health.gov.au>; s22 [redacted] @health.gov.au>; s22 [redacted] @Health.gov.au>; s22 [redacted] @Health.gov.au>; s22 [redacted] @health.gov.au>; s22 [redacted] @health.gov.au>; s22 [redacted] @Health.gov.au>; s22 [redacted] @health.gov.au>; s22 [redacted] @health.gov.au>; MBD Regulations s47E(d) [redacted] @health.gov.au>; s22 [redacted] @health.gov.au>; s22 [redacted] @health.gov.au>; s22 [redacted] @health.gov.au>; s22 [redacted] @Health.gov.au>; s22 [redacted] @Health.gov.au>; s22 [redacted] @Health.gov.au>
Subject: FOR ACTION (by COB Friday 4 October): DIs for 1 July 2025 MBS legislative changes [SEC=OFFICIAL]

Good morning/afternoon,

You are receiving this email as the Medicare Implementation and Regulations Section (MIRS) understands that you may have proposed regulatory changes to the Medicare Benefits Schedule (MBS) commencing **1 July 2025**.

To CC'ed recipients, this email is *FYI only* regarding the timing of 1 July 2025 MBS changes as MIRS currently is unaware of any regulatory changes required by your teams. Please advise MIRS ASAP if this is not the case.

FOR ACTION by COB Friday 4 October: AS approved Drafting Instructions (DIs)

Please complete the attached drafting instructions template for regulatory changes to the MBS, and return to the MBD Regulations inbox at s47E(d) [redacted] @health.gov.au with Assistant Secretary clearance by ***COB Friday 4 October 2024.*** Please note that this earlier timeframe is in anticipation of the next Federal Election being called in 2024.

s47C, s47E(d)

[redacted]

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

s47C, s47E(d)

[redacted]

If you have any questions, please reach out to MIRS at s47E(d) [redacted] @health.gov.au.

Regards,

s22 [redacted]

s22 [redacted]

Medicare Implementation and Regulations Section

MBS Policy and Specialist Programs Branch
Medicare Benefits & Digital Health Division | Health Resourcing Group
Australian Government Department of Health and Aged Care
M: s22 [redacted]
Location: Sirius Building
GPO Box 9848, Canberra ACT 2601, Australia

The Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Authorised Prescriber	Product Profile	Product Presentation	Number of New Patients	Number of Prescription or Devices
MAP23-0044142	Lutetium-177 Prostate Specific Membrane Antigen (PSMA)	Lutetium-177 Prostate Specific Membrane Antigen (PSMA)	1	1
MAP23-0044111	F18\18F-DCFPyL Prostate Specific Membrane Antigen (PSMA)	F18\18F-DCFPyL Prostate Specific Membrane Antigen (PSMA)	929	929
MAP23-0044452	Lutetium-177 Octreotate (177 Lu-DOTATATE)	Lutetium-177 Octreotate (177 Lu-DOTATATE)	0	0
MAP23-0044141	F18\18F-Sodium Fluoride (NaF)	F18\18F-Sodium Fluoride (NaF)	0	0

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

TGA use only
Reference: s47F

Special Access Scheme – Category A

Patient details

Patient initials	Gender	DOB	MRN
s47F			s47F

Diagnosis(es)	Previous SAS No.
Metastatic Prostate Cancer	

Indication
Metastatic Prostate Cancer

Clinical justification for use of product
Not applicable for SAS Category A notifications

Product details

Medicine or Biological		Medical Device	
Trade Name LuPSMA i&t		**Trade name**	
Active ingredient(s) 177Lu-PSMA i&t		**Product description**	
Dosage form Injection	**Strength** 8 Gigabecquerel	**Model Number / Variant**	
Route of administration Intravenous	**Dose & frequency** As per prescription	**Sponsor / Supplier**	**Manufacturer**
Sponsor / Supplier ANSTO		**No of units to be supplied**	**Intended date of use**
Expected duration of treatment 4 Hour(s)		**Expected duration of treatment**	

Health Practitioner Details

Prescribing health practitioner details		Submitter details (if different from prescriber)	
First name s47F	**Surname**	**Business or practice name** Liverpool Hospital	
AHPRA ID s47F	**Health practitioner type**	**First name** s47F	**Surname**
Email s47F		**Health practitioner type** Medical Radiation Practitioner	
Principal practice address s47G(1)(a)		**Email** s47F	
Submitter's signature **Electronically signed by** s47F		**Date** 15 Jan 2025	

Supporting information

Additional information

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

TGA use only
Reference: s47F

Special Access Scheme – Category A

Patient details

Patient initials	Gender	DOB	MRN
s47F			s47F

Diagnosis(es)	Previous SAS No.
Metastatic Prostate Cancer	

Indication
Metastatic Prostate Cancer

Clinical justification for use of product
Not applicable for SAS Category A notifications

Product details

Medicine or Biological		Medical Device	
Trade Name LuPSMA i&t		**Trade name**	
Active ingredient(s) 177Lu-PSMA i&t		**Product description**	
Dosage form Injection	**Strength** 8 Gigabecquerel	**Model Number / Variant**	
Route of administration Intravenous	**Dose & frequency** As per prescription	**Sponsor / Supplier**	**Manufacturer**
Sponsor / Supplier ANSTO		**No of units to be supplied**	**Intended date of use**
Expected duration of treatment 4 Hour(s)		**Expected duration of treatment**	

Health Practitioner Details

Prescribing health practitioner details		Submitter details (if different from prescriber)	
First name s47F	**Surname**	**Business or practice name** Liverpool Hospital	
AHPRA ID s47G(1)(a)	**Health practitioner type** Medical Practitioner	**First name** s47F	**Surname**
Email s47F		**Health practitioner type** Medical Radiation Practitioner	
Principal practice address s47G(1)(a)		**Email** s47F	
Submitter's signature **Electronically signed by** Mr s47F		**Date** 15 Jan 2025	

Supporting information

Additional information

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

TGA use only
Reference: s47F

Special Access Scheme – Category A

Patient details

Patient initials	Gender	DOB	MRN
s47	s47F	s47F	s47F

Diagnosis(es)	Previous SAS No.
Metastatic Prostate Cancer	

Indication
Metastatic Prostate Cancer

Clinical justification for use of product
Not applicable for SAS Category A notifications

Product details

Medicine or Biological		Medical Device	
Trade Name		**Trade name**	
Active ingredient(s) 177Lutetium PSMA I&T		**Product description**	
Dosage form Injection	**Strength** 7.4 Gigabecquerel	**Model Number / Variant**	
Route of administration Intravenous Infusion	**Dose & frequency** 7.4 onces	**Sponsor / Supplier**	**Manufacturer**
Sponsor / Supplier		**No of units to be supplied**	**Intended date of use**
Expected duration of treatment 20 Minute(s)		**Expected duration of treatment**	

Health Practitioner Details

Prescribing health practitioner details		Submitter details (if different from prescriber)	
First name s47F	**Surname**	**Business or practice name**	
AHPRA ID s47G(1)(a)	**Health practitioner type** Medical Practitioner	**First name**	**Surname**
Email s47F		**Health practitioner type**	
Principal practice address s47G(1)(a)		**Email**	
Submitter's signature **Electronically signed by** Prof s47F s47G(1)(a)		**Date** 23 Jan 2025	

Supporting information

Additional information

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

TGA use only

Reference: s47F

Special Access Scheme – Category A

Patient details

Patient initials	Gender	DOB	MRN
s47F			s47F

Diagnosis(es)	Previous SAS No.
Metastatic castrate resistant Prostate Cancer	

Indication
Metastatic Prostate Cancer

Clinical justification for use of product
Not applicable for SAS Category A notifications

Product details

Medicine or Biological		Medical Device	
Trade Name		**Trade name**	
Active ingredient(s) 177Lutetium PSMA I&T		**Product description**	
Dosage form Injection	**Strength** 8 Gigabecquerel	**Model Number / Variant**	
Route of administration Intravenous Infusion	**Dose & frequency** 8GBq once	**Sponsor / Supplier**	**Manufacturer**
Sponsor / Supplier		**No of units to be supplied**	**Intended date of use**
Expected duration of treatment 20 Minute(s)		**Expected duration of treatment**	

Health Practitioner Details

Prescribing health practitioner details		Submitter details (if different from prescriber)	
First name s47F	**Surname** s47F	**Business or practice name**	
AHPRA ID s47G(1)(a)	**Health practitioner type** Medical Practitioner	**First name**	**Surname**
Email s47G(1)(a)		**Health practitioner type**	
Principal practice address s47G(1)(a)		**Email**	
Submitter's signature **Electronically signed by** Dr s47F s47G(1)(a)		**Date** 23 Jan 2025	

Supporting information

Additional information

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

TGA use only
Reference: s47F

Special Access Scheme – Category A

Patient details

Patient initials	Gender	DOB	MRN
s47F			s47F
Diagnosis(es) Metastatic Prostate Cancer			**Previous SAS No.** s47F
Indication Prostate Cancer			
Clinical justification for use of product Not applicable for SAS Category A notifications			

Product details

Medicine or Biological		Medical Device	
Trade Name		**Trade name**	
Active ingredient(s) 177Lutetium PSMA I&T		**Product description**	
Dosage form Injection	**Strength** 8.00 Gigabecquerel	**Model Number / Variant**	
Route of administration Intravenous Infusion	**Dose & frequency** 8GBq Once	**Sponsor / Supplier**	**Manufacturer**
Sponsor / Supplier		**No of units to be supplied**	**Intended date of use**
Expected duration of treatment 20 Minute(s)		**Expected duration of treatment**	

Health Practitioner Details

Prescribing health practitioner details		Submitter details (if different from prescriber)	
First name s47F	**Surname**	**Business or practice name**	
AHPRA ID s47G(1)(a)	**Health practitioner type** Medical Practitioner	**First name**	**Surname**
Email s47F		**Health practitioner type**	
Principal practice address s47G(1)(a)		**Email**	
Submitter's signature Electronically signed by Dr s47F s47G(1)(a)		**Date** 23 Jan 2025	

Supporting information

Additional information

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

TGA use only
Reference: s47F

Special Access Scheme – Category A

Patient details

Patient initials	Gender	DOB	MRN
s47F			s47F
Diagnosis(es) Metastatic Prostate Cancer			**Previous SAS No.** s47F
Indication Metastatic Castrate Resistant Prostate Cancer			
Clinical justification for use of product Not applicable for SAS Category A notifications			

Product details

Medicine or Biological		Medical Device	
Trade Name		**Trade name**	
Active ingredient(s) Lutetium-177 Prostate Specific Membrane Antigen (PSMA)		**Product description**	
Dosage form Injection	**Strength** 8 Gigabecquerel	**Model Number / Variant**	
Route of administration Intravenous	**Dose & frequency** As per prescription	**Sponsor / Supplier**	**Manufacturer**
Sponsor / Supplier Quantum Pharma		**No of units to be supplied**	**Intended date of use**
Expected duration of treatment 4 Hour(s)		**Expected duration of treatment**	

Health Practitioner Details

Prescribing health practitioner details		Submitter details (if different from prescriber)	
First name s47F	**Surname**	**Business or practice name** San Radiology and Nuclear Medicine	
AHPRA ID s47G(1)(a)	**Health practitioner type** Medical Practitioner	**First name** s47F	**Surname**
Email s47F		**Health practitioner type** Medical Radiation Practitioner	
Principal practice address s47G(1)(a)		**Email** s47F	
Submitter's signature **Electronically signed by** Mr s47F s47G(1)(a)		**Date** 03 Feb 2025	

Supporting information

Additional information

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

TGA use only

Reference: MA25-1421826

Special Access Scheme – Category A

Patient details

Patient initials	Gender	DOB	MRN
s47	s47F	s47F	s47F

Diagnosis(es)	Previous SAS No.
Metastatic Prostate Cancer	

Indication
Metastatic Castrate Resistant Prostate Cancer

Clinical justification for use of product
Not applicable for SAS Category A notifications

Product details

Medicine or Biological

Trade Name			
Active ingredient(s) Lutetium-177 Prostate Specific Membrane Antigen (PSMA)			
Dosage form Injection	**Strength** 8 Gigabecquerel		
Route of administration Intravenous	**Dose & frequency** As per prescription	**Sponsor / Supplier**	**Manufacturer**
Sponsor / Supplier s47G(1)(a)		**No of units to be supplied**	**Intended date of use**
Expected duration of treatment 4 Hour(s)		**Expected duration of treatment**	

Medical Device

Trade name	
Product description	
Model Number / Variant	
Sponsor / Supplier	**Manufacturer**
No of units to be supplied	**Intended date of use**
Expected duration of treatment	

Health Practitioner Details

Prescribing health practitioner details

First name	Surname
s47F	s47F
AHPRA ID s47G(1)(a)	**Health practitioner type** Medical Practitioner
Email s47F	
Principal practice address s47G(1)(a)	
Submitter's signature **Electronically signed by** Mr s47F s47G(1)(a)	**Date** 04 Feb 2025

Submitter details (if different from prescriber)

Business or practice name	
s47G(1)(a)	
First name s47F	**Surname** s47F
Health practitioner type Medical Radiation Practitioner	
Email s47F ah.org.au	

Supporting information

Additional information

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

TGA use only

Reference: MA25-1438851

Special Access Scheme – Category A

Patient details

Patient initials	Gender	DOB	MRN
s47	s47F	s47F	s47F

Diagnosis(es)	Previous SAS No.
Metastatic Prostate Cancer	s47F

Indication
Metastatic Castrate Resistant Prostate Cancer

Clinical justification for use of product
Not applicable for SAS Category A notifications

Product details

Medicine or Biological

Trade Name		
Active ingredient(s) Lutetium-177 Prostate Specific Membrane Antigen (PSMA)		
Dosage form Injection	**Strength** 8 Gigabecquerel	
Route of administration Intravenous	**Dose & frequency** As per prescription	
Sponsor / Supplier s47G(1)(a)		
Expected duration of treatment 4 Hour(s)		

Medical Device

Trade name		
Product description		
Model Number / Variant		
Sponsor / Supplier	**Manufacturer**	
No of units to be supplied	**Intended date of use**	
Expected duration of treatment		

Health Practitioner Details

Prescribing health practitioner details

First name	Surname
s47F	
AHPRA ID s47G(1)(a)	**Health practitioner type** Medical Practitioner
Email s47F	
Principal practice address s47G(1)(a)	
Submitter's signature **Electronically signed by** Mr s47F s47G(1)(a)	

Submitter details (if different from prescriber)

Business or practice name	
s47F	
First name s47F	**Surname**
Health practitioner type Medical Radiation Practitioner	
Email s47F	
Date 18 Feb 2025	

Supporting information

Additional information

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

TGA use only

Reference: MA25-1439708

Special Access Scheme – Category A

Patient details

Patient initials	Gender	DOB	MRN
s47	s47F	s47F	s47F

Diagnosis(es)
Metastatic Prostate Cancer

Previous SAS No.

Indication
Metastatic Prostate Cancer

Clinical justification for use of product
Not applicable for SAS Category A notifications

Product details

Medicine or Biological

Trade Name
LuPSMA i&t

Active ingredient(s)
177Lu-PSMA i&t

Dosage form	Strength
Injection	8 Gigabecquerel

Route of administration	Dose & frequency
Intravenous	As per prescription

Sponsor / Supplier
s47G(1)

Expected duration of treatment
4 Hour(s)

Medical Device

Trade name

Product description

Model Number / Variant

Sponsor / Supplier | **Manufacturer**

No of units to be supplied | **Intended date of use**

Expected duration of treatment

Health Practitioner Details

Prescribing health practitioner details

First name	Surname
s47F	

AHPRA ID	Health practitioner type
s47G(1)(a)	Medical Practitioner

Email
s47F

Principal practice address
s47G(1)(a)

Submitter details (if different from prescriber)

Business or practice name
s47G(1)(a)

First name	Surname
s47F	

Health practitioner type
Medical Radiation Practitioner

Email
s47F health.nsw.gov.au

Submitter's signature
Electronically signed by
Mr s47F s47G(1)(a)

Date
19 Feb 2025

Supporting information

Additional information

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

s47F, s47G(1)(a)

Notice of decision to grant an approval
under paragraph 19(1)(a) of the *Therapeutic Goods Act 1989*
(Special Access Scheme – Category B)

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

I refer to the application made on 17 Jul 2024 seeking approval by the Secretary of the Department of Health and Aged Care to a health practitioner for the importation into, the exportation from, or the supply in Australia of specified therapeutic goods (namely, a specified medicine) that are not registered goods, listed goods or exempt goods for use in the treatment of another person in accordance with paragraph 19(1)(a) of the *Therapeutic Goods Act 1989* (**the Act**).

This is a notice of decision given to you in accordance with subsection 19(4) of the Act.

Decision

I am a delegate of the Secretary of the Department of Health and Aged Care for the purposes of section 19(1) of the Act. I have decided to grant approval to s47F, s47G(1)(a) (the **approval holder**) identified in column 1 of Schedule 1 to this notice to import into, export from, or supply in Australia the specified medicine identified in column 2 of Schedule 1 for use in the treatment of the patient identified in column 3.

Reasons for decision

I have decided to grant this approval having considered the application made on 17 Jul 2024 and the information provided with that application.

In making this decision, I am satisfied that:

(a) the specified medicine is not included in the Australian Register of Therapeutic Goods (**Register**) or otherwise exempt from the requirement to include the specified medicine in the Register;

(b) the importation into, the exportation from, or the supply in Australia of the specified medicine is for use in the treatment of another person; and

(c) the approval holder is a health practitioner within the meaning of the Act.

Conditions

This approval is granted subject to the following conditions imposed by me in accordance with subsection 19(1) of the Act:

1. the approval holder must only import into, export from, or supply in Australia the specified medicine for use in the treatment of the patient in the manner described in the application;
2. the approval holder, and the patient (or the person with the legal authority to consent to the treatment on behalf of the patient) must accept responsibility for the outcome of the use of the specified medicine;
3. the approval holder must obtain and record informed consent from each patient (or the person with the legal authority to consent to the treatment on behalf of the patient) in relation to the proposed use of the product, in accordance with professional practice standards and the AHPRA Code of Conduct;
4. the approval holder must report adverse events or defects associated with the use of the specified medicine to the TGA within 15 calendar days after the approval holder becomes aware of the adverse event. The preferred reporting route is via the online portal https://aems.tga.gov.au;
5. the approval holder must adhere to all standards of professional practice and conduct, as governed by the relevant professional regulatory authority.

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Please note that it is the responsibility of the approval holder to arrange for the importation into, exportation from, or the supply in Australia of the specified medicine and to provide evidence of this approval to the person or persons with whom the importation into, the exportation from, or the supply in Australia is arranged.

Additional restrictions may be placed on the importation of therapeutic goods as outlined below. You will need to check with the relevant agencies to obtain permission if required.

- *Customs (Prohibited Imports) Regulations 1956* - import permits and licences are required for substances controlled under these Regulations. Contact the Office of Drug Control at NCS@health.gov.au for further information.
- *Biosecurity Act 2015* - permission may be required prior to importing any material of biological origin (human, animal, plant or microbial). Contact the Department of Agriculture, Water and the Environment at imports@agriculture.gov.au for information.
- *Environment Protection and Biodiversity Conservation Act 1999* - permission may be required prior to importing endangered species. Contact the Department of Agriculture, Water and the Environment at wps@awe.gov.au for information.
- *Gene Technology Act 2000* – permission may be required prior to importing genetically modified organisms. Email the Office of the Gene Technology Regulator (OGTR) at ogtr@health.gov.au for information.
- State and territory requirements - contact the relevant state/territory health department for further information.

PO Box 100 Woden ACT 2606 ABN 40 939 406 804
Phone: 1800 020 653 Fax: 02 6203 1605 Email: info@tga.gov.au
https://www.tga.gov.au

Period of approval

This approval has effect for a period of 24 Month(s) commencing on the date of this notice, unless the Secretary (or a delegate) decides to revoke the approval.

Dated 17 Jul 2024

s47F
Delegate of the Secretary
Therapeutic Goods Administration

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

PO Box 100 Woden ACT 2606 ABN 40 939 406 804
Phone: 1800 020 653 Fax: 02 6203 1605 Email: info@tga.gov.au
https://www.tga.gov.au

Schedule 1

Reference: MB24-1233606

Column 1 Approval holder	Column 2 Specified medicine	Column 3 Patient	Column 4 Conditions
s47G(1)(a), s47F [redacted] s47G(1)(a) [redacted]	*Medicine:* Lutetium-177 Prostate Specific Membrane Antigen (PSMA) *Product description:* Injection	s47F [redacted] [redacted]	*Purpose:* Metastatic prostate cancer *Dosage:* As per prescription

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

PO Box 100 Woden ACT 2606 ABN 40 939 406 804
Phone: 1800 020 653 Fax: 02 6203 1605 Email: info@tga.gov.au
https://www.tga.gov.au

Request for reconsideration of an initial decision

This decision is a reviewable initial decision under section 60 of the Act. Under section 60, a person whose interests are affected by a 'reviewable' initial decision, can seek reconsideration of the initial decision.

As this document constitutes written notice of the making of an initial decision being given by the Secretary, a request for reconsideration of this initial decision must be given to the Minister in writing within 90 (calendar) days after the initial decision notice is given and be accompanied by any information that you wish to have considered by the Minister. A request for reconsideration given to the Minister outside the statutory 90 day reconsideration period cannot be accepted.

The Minister may either personally undertake a request for reconsideration of an initial decision or delegate this function to an officer of the Department with the appropriate delegation.

Under section 60(3A) of the Act, the Minister (or the Minister's delegate) is not able to consider any information provided after the making of a request for reconsideration of an initial decision unless the information is provided in response to a request from the Minister (or the Minister's delegate), or it is information that indicates that the quality, safety or efficacy of the relevant therapeutic goods is unacceptable.

Guidelines for requesting reconsideration of an initial decision

Prior to requesting reconsideration of an initial decision, persons affected by an initial decision are advised to refer to the TGA website <https://www.tga.gov.au/resources/resource/guidance/guidance-requesting-reconsideration-initial-decision> for specific information and detailed guidance for making a request for reconsideration. A request for reconsideration should then be made in writing, signed and dated by the person requesting reconsideration and should include the following:

- a copy of the initial decision notification letter, i.e. this letter (or other evidence of notification);
- identify, and describe with as much specificity as possible, which component(s) of the initial decision should be reconsidered and set out the reasons why reconsideration is requested;
- any information/documentation in support of the request, clearly labelled to correspond with (any or each of) the reasons why reconsideration is requested; and

an email address nominated for the purposes of receiving correspondence in relation to the request for reconsideration. All requests for reconsideration should be given to the Minister by email:

Email: **'decision.review@health.gov.au'**

Subject: **"<insert name of person/company making request>** - Request for Reconsideration Under Section 60 of the Therapeutic Goods Act 1989"

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

PO Box 100 Woden ACT 2606 ABN 40 939 406 804
Phone: 1800 020 653 Fax: 02 6203 1605 Email: info@tga.gov.au
https://www.tga.gov.au

Requests for reconsideration that include material which cannot be attached to a single email, may be submitted under multiple, sequentially numbered emails (e.g. "… - Email 1 of 3", "… - Email 2 of 3" etc). All sequentially numbered emails must be given to the Minister on the same date.
Under section 60 of the Act, the decision upon reconsideration by the Minister (or the Minister's delegate) must be to either 'confirm', 'revoke' or 'revoke and substitute' the initial decision. The Minister (or the Minister's delegate) must give notice in writing of the outcome of the decision upon reconsideration to the person whose interests are affected, within 60 (calendar) days after making a request for reconsideration. If the Minister (or the Minister's delegate) fails to give such notice within 60 days, the Minister (or the Minister's delegate) is deemed to have confirmed the initial decision.

Subject to the Administrative Appeals Tribunal Act 1975 (AAT Act), if you are dissatisfied with the decision upon reconsideration by the Minister (or the Minister's delegate), you can apply to the Administrative Appeals Tribunal (AAT) for a review of that decision upon reconsideration.

NOTE: This initial decision remains in effect unless and until it is revoked or revoked and substituted by the Minister (or the Minister's delegate) as a result of a request for reconsideration under section 60 of the Act OR is set aside, varied or remitted by the AAT or is otherwise overturned or stayed.

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

PO Box 100 Woden ACT 2606 ABN 40 939 406 804
Phone: 1800 020 653 Fax: 02 6203 1605 Email: info@tga.gov.au
https://www.tga.gov.au

Australian Government

Department of Health
Therapeutic Goods Administration

Dr s47F

Email: s47F

Our Reference: MAP21-0024486

Dear s47F

Notice of decision to grant an authority under subsection 19(5) of the Therapeutic Goods Act 1989 (Authorised Prescriber Scheme) in relation to:

Product: Lutetium-177 PSMA - - Injection

I refer to your application dated 09 Nov 2021 seeking an authority to supply specified therapeutic goods for use in the treatment of humans, to a specified class of recipients under subsection 19(5) of the *Therapeutic Goods Act 1989* (the Act).

Decision

As a delegate of the Secretary of the Department of Health under subsection 19(5) of the Act, I have decided to grant an authority:

- to the specified medical practitioner identified in column 1 of **Schedule 1** to this notice ('the Authorised Prescriber');
- to supply the specified therapeutic goods, or class of goods, identified in column 2 of **Schedule 1** for the indication(s) specified in column 3;
- for supply to a class of recipients (patients) suffering from a life-threatening, or otherwise serious illness or condition.

When supplying the goods, you must comply with:

- the treatment directions (if any) identified in column 4 of **Schedule 1** (subsection 19(7) of the Act and subregulation 12B(3) of the *Therapeutic Goods Regulations 1990* (**the Regulations**) refer); and
- the conditions referred to below.

See further below for the period this authority is in effect.

Reasons

I grant this authority having considered the information in the application.

I am satisfied that each of the following requirements is met:

- **Class of medical practioners**

  The Authorised Prescriber is included in the class of medical practitioners being medical practitioners engaged in clinical practice in or outside a hospital (paragraph 19(6)(a) of the Act and subregulation 12B(1) of the Regulations refer);

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

- **Requirements of subregulation 12B(1B)**
  The proposed supply of the medicine by the Authorised Prescriber is consistent with the requirements in subregulation 12B(1B) of the Regulations relating to the active ingredient (including strength and concentration, as applicable), dosage form, route of administration and indication;

- **Class of recipients**
  The class of recipients (patients) is to consist of persons each of whom is suffering from a life-threatening, or otherwise serious, illness or condition (paragraph 19(6)(b) of the Act and subregulation 12B(2) refers).

Conditions

This authority is granted subject to the following conditions (if any) imposed by me in accordance with subsection 19(5A) of the Act:

1.The authorised prescriber ('you') must only prescribe the specified therapeutic goods or class of goods ('the product') for patients under your immediate care.

2.You must obtain informed consent in writing from each patient (or guardian) in relation to the proposed use of the product. Before obtaining consent, you must inform the patient that the product is not in the Australian Register of Therapeutic Goods and has not been evaluated for quality, safety and efficacy in the Australian context.

3.You must instruct the patient (or guardian) to return any unused product to you or to a pharmacy for destruction.

4.Subject to condition 5, you must report any suspected adverse reaction to the product to the TGA within 15 calendar days after becoming aware of the reaction.

5.You must report any fatal or life-threatening adverse reaction to the product to the TGA within 7 calendar days after becoming aware of the reaction. You must follow up with a complete report (if not provided within the 7 calendar day period) within 8 additional calendar days.

6.[As relevant – i.e, where authority granted on basis of ethics committee approval/ specialist college endorsement.] You must also report any suspected adverse reaction to the product to the ethics committee or specialist college which provided approval or endorsement.

7.[As relevant – i.e, where authority granted on basis of ethics committee approval/ specialist college endorsement] You must continue to have the approval of the ethics committee or the endorsement of the specialist college to supply the product.

8.[As relevant – i.e, where authority granted on basis of ethics committee approval/ specialist college endorsement]. If the ethics committee or specialist college suspends, withdraws or revokes the approval or endorsement, you must notify the TGA within 7 calendar days after becoming aware of this.

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

9.[As relevant to medicinal cannabis cases] If any other medical practitioners are treating the patient's condition, you must notify those practitioners that you have prescribed a medicinal cannabis product for the patient and keep the practitioners informed of the patient's progress.

10.[As relevant to medicinal cannabis cases] You must only prescribe the product for patients aged 18 years or over. If your registration as a medical practitioner is suspended or cancelled, you must notify the TGA within 5 business days of you receiving notification of the suspension or cancellation.

This product is included in Schedule 4 of the Customs (Prohibited Imports) Regulations 1956. The Drug Control Section (DCS) of the Department of Health is responsible for issuing import permits and licences for substances controlled under Schedule 4 of these Regulations. The contact email address for DCS is DCS@health.gov.au

Patients should not drive or operate machinery while being treated with medicinal cannabis. In addition, measurable concentrations of THC (tetrahydrocannabinol – the main psychoactive substance in cannabis) can be detected in urine many days after the last dose. It may take up to five days for 80 to 90 per cent of the dose to be excreted. Drug-driving is a criminal offence, and patients should discuss the implications for safe and legal driving with their doctor.

Other information

Reporting requirements

Under regulation 47B of the Regulations, you are required to report details of the supply of the therapeutic goods to the Secretary on a six monthly basis. The reporting periods are for 1 January to 30 June, and 1 July to 31 December, respectively.

Reports must be provided within one calendar month of the reporting period ending. The report should be provided using the SAS Online System, available at http:/sas.tga.gov.au. Alternatively, the 'Six monthly report – supply of unapproved product' form can be found on the TGA website at https://www.tga.gov.au/sites/default/files/authorised-prescriber-six-monthly-report-template.pdf

Review rights

Your review rights in relation to this decision are outlined at **Schedule 2** to this notice.

Please contact the Authorised Prescriber team by phone on 02 6289 4632 or email to authorised.prescribers@health.gov.au for further queries regarding this matter.

Period authority is in effect

This authority has effect for the period commencing on the date of this notice until 09 Nov 2023, unless the Secretary (or a delegate) decides to revoke the authority sooner.

Dated 10 Nov 2021

s47F

Delegate of the Secretary

Therapeutic Goods Administration

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Schedule 1:

Details of authority granted under subsection 19(5) of the Therapeutic Goods Act 1989

Reference (MAP21-0024486)

Column 1 Authorised Prescriber	Column 2 Specified therapeutic goods (or class of goods)	Column 3 Specified indication(s)	Column 4 Treatment directions (if any)
s4 7F , s4	Lutetium-177 PSMA - - Injection 8 Gigabecquerel Injection Intravenous	For the following indication(s): AP139-Treatment of metastatic castration resistant prostate cancer	

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Schedule 2:
Request for reconsideration of an initial decision

This decision is a 'reviewable' initial decision under section 60 of the Act. Under section 60, a person whose interests are affected by a 'reviewable' initial decision, can seek reconsideration of the initial decision.

As this document constitutes written notice of the making of an initial decision being given by the Secretary, a request for reconsideration of this initial decision must be given to the Minister within 90 days and be accompanied by any information that you wish to have considered. A request for reconsideration given to the Minister outside the statutory 90 day reconsideration period cannot be accepted. The Minister may either personally undertake a request for reconsideration of an initial decision or delegate this function to an officer of the Department with the appropriate delegation.

Under section 60(3A) of the Act, the Minister (or the Minister's delegate) is not able to consider any information provided after the making of a request for reconsideration of an initial decision unless the information is provided in response to a request from the Minister (or the Minister's delegate), or it is information that indicates that the quality, safety or efficacy of the relevant therapeutic goods is unacceptable.

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Guidelines for requesting reconsideration of an initial decision

A request for reconsideration should be made in writing, signed and dated by the person requesting reconsideration, should be titled "**<insert person/company name> - Request for Reconsideration Under Section 60 of the *Therapeutic Goods Act 1989***" and should include the following:

- a copy of the initial decision notification letter, i.e. this letter (or other evidence of notification);
- identify, and describe with as much specificity as possible, which component(s) of the initial decision should be reconsidered and set out the reasons why reconsideration is requested;
- any information/documentation in support of the request, clearly labelled to correspond with (any or each of) the reasons why reconsideration is requested; and
- an email address nominated for the purposes of receiving correspondence in relation to the request for reconsideration.

All requests for reconsideration should be given to the Minister by email:

Email: '**minister.hunt.DLO@health.gov.au**' and cc'ed to: '**decision.review@tga.gov.au**'

Requests for reconsideration that include dossiers (or similar bulk material) that cannot easily be attached to the request given first by email, may then be submitted on a USB drive or CD sent by express post or registered mail to:

Mail: **Minister for Health**
Suite M1 41
c/- Parliament House
CANBERRA ACT 2600

Subject to the *Administrative Appeals Tribunal Act 1975* (AAT Act), if you are dissatisfied with the decision upon reconsideration by the Minister (or the Minister's delegate), you can apply to the Administrative Appeals Tribunal (AAT) for a review of that decision upon reconsideration.

NOTE: This initial decision remains in effect unless and until it is revoked or revoked and substituted by the Minister (or the Minister's delegate) as a result of a request for reconsideration under section 60 of the Act OR is set aside, varied or remitted by the AAT or is otherwise overturned or stayed.

Australian Government

Department of Health
Therapeutic Goods Administration

s47F

Our Reference: MAP22-0040266

Dear Dr s47F

Notice of decision to grant an authority under subsection 19(5) of the *Therapeutic Goods Act 1989* (Authorised Prescriber Scheme) in relation to:

Product: Lutetium-177 PSMA - Injection

I refer to your application dated 04 Oct 2022 seeking an authority to supply specified therapeutic goods for use in the treatment of humans, to a specified class of recipients under subsection 19(5) of the *Therapeutic Goods Act 1989* (**the Act**).

Decision

As a delegate of the Secretary of the Department of Health under subsection 19(5) of the Act, I have decided to grant an authority:

- to the specified medical practitioner identified in column 1 of **Schedule 1** to this notice ('the Authorised Prescriber');
- to supply the specified therapeutic goods, or class of goods, identified in column 2 of **Schedule 1** for the indication(s) specified in column 3;
- for supply to a class of recipients (patients) suffering from a life-threatening, or otherwise serious illness or condition.

When supplying the goods, you must comply with:

- the treatment directions (if any) identified in column 4 of **Schedule 1** (subsection 19(7) of the Act and subregulation 12B(3) of the *Therapeutic Goods Regulations 1990* (**the Regulations**) refer); and
- the conditions referred to below.

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Reasons

I grant this authority having considered the information in the application.

I am satisfied that each of the following requirements is met:

- **Class of medical practitioners**
  The Authorised Prescriber is included in the class of medical practitioners being medical practitioners engaged in clinical practice in or outside a hospital (paragraph 19(6)(a) of the Act and subregulation 12B(1) of the Regulations refer);

- **Requirements of subregulation 12B(1B) or 12B(1C)**
  The proposed supply of the medicine by the Authorised Prescriber is consistent with the requirements in subregulation 12B(1B) or 12B(1C) of the Regulations relating to the active

ingredient (including strength and concentration, as applicable), dosage form, route of administration and indication;

- **Class of recipients**
  The class of recipients (patients) is to consist of persons each of whom is suffering from a life-threatening, or otherwise serious, illness or condition (paragraph 19(6)(b) of the Act and subregulation 12B(2) refers).

Conditions

This authority is granted subject to the following conditions (if any) imposed by me in accordance with subsection 19(5A) of the Act:
The Authorised Prescriber ('you') must only prescribe the specified therapeutic goods or class of goods ('the product') for patients under your immediate care.

If your registration as a medical practitioner is suspended or cancelled, you must notify the TGA within 5 business days of you receiving notification of the suspension or cancellation.

You must obtain informed consent in writing from each patient (or guardian) in relation to the proposed use of the product. Before obtaining consent, you must inform the patient that the product is not in the Australian Register of Therapeutic Goods and has not been evaluated for quality, safety and efficacy in the Australian context.

You must instruct the patient (or guardian) to return any unused product to you or to a pharmacy for destruction.

You must report any suspected adverse reaction to the product to the TGA within 15 calendar days after becoming aware of the reaction.

You must report any fatal or life-threatening adverse reaction to the product to the TGA within 7 calendar days after becoming aware of the reaction. You must follow up with a complete report (if not provided within the 7 calendar day period) within 8 additional calendar days.

You must ensure that other medical practitioners involved in the treatment of a patient's conditions are kept informed of the use of the product and progress to ensure good medicine practice.

Other information

Reporting requirements

Under regulation 47B of the Regulations, you are required to report details of the supply of the therapeutic good to the Secretary on a six monthly basis. The reporting periods are for 1 January to 30 June, and 1 July to 31 December, respectively. Reports must be provided within one calendar month of the reporting period ending. It is preferred the report is provided using the SAS & AP Online System, available at https://compliance.health.gov.au/sas/ however a paper form is available from the Authorised Prescriber webpage for exceptional circumstances.

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Review rights

Your review rights in relation to this decision are outlined at **Schedule 2** to this notice.
Please contact the Authorised Prescriber team by phone on 02 6289 4632 or email to authorised.prescribers@health.gov.au for further queries regarding this matter.

Period authority is in effect

This authority has effect for the period commencing on the date of this notice until 05 Oct 2027, unless the Secretary (or a delegate) decides to revoke the authority sooner.
Dated 07 Oct 2022

s47F
Delegate of the Secretary
Therapeutic Goods Administration

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Schedule 1:

Details of authority granted under subsection 19(5) of the *Therapeutic Goods Act 1989*

Reference (MAP22-0040266)

Column 1 Authorised Prescriber	Column 2 Specified therapeutic goods (or class of goods)	Column 3 Specified indication(s)	Column 4 Treatment directions (if any)
s47F, s47G (1	Lutetium-177 PSMA - Injection 8 Gigabecquerel Injection Intravenous	For the following indication(s): AP155-Treatment of metastatic castration resistant prostate cancer	

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Schedule 2:
Request for reconsideration of an initial decision

This decision is a 'reviewable' initial decision under section 60 of the Act. Under section 60, a person whose interests are affected by a 'reviewable' initial decision, can seek reconsideration of the initial decision.

As this document constitutes written notice of the making of an initial decision being given by the Secretary, a request for reconsideration of this initial decision must be given to the Minister within 90 days and be accompanied by any information that you wish to have considered. A request for reconsideration given to the Minister outside the statutory 90 day reconsideration period cannot be accepted. The Minister may either personally undertake a request for reconsideration of an initial decision or delegate this function to an officer of the Department with the appropriate delegation.

Under section 60(3A) of the Act, the Minister (or the Minister's delegate) is not able to consider any information provided after the making of a request for reconsideration of an initial decision unless the information is provided in response to a request from the Minister (or the Minister's delegate), or it is information that indicates that the quality, safety or efficacy of the relevant therapeutic goods is unacceptable.

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Guidelines for requesting reconsideration of an initial decision

A request for reconsideration should be made in writing, signed and dated by the person requesting reconsideration, should be titled "**<insert person/company name> - Request for Reconsideration Under Section 60 of the *Therapeutic Goods Act 1989***" and should include the following:

- a copy of the initial decision notification letter, i.e. this letter (or other evidence of notification);
- identify, and describe with as much specificity as possible, which component(s) of the initial decision should be reconsidered and set out the reasons why reconsideration is requested;
- any information/documentation in support of the request, clearly labelled to correspond with (any or each of) the reasons why reconsideration is requested; and
- an email address nominated for the purposes of receiving correspondence in relation to the request for reconsideration.

All requests for reconsideration should be given to the Minister by email:

Email: '**minister.hunt.DLO@health.gov.au**' and cc'ed to: '**decision.review@tga.gov.au**'

Requests for reconsideration that include dossiers (or similar bulk material) that cannot easily be attached to the request given first by email, may then be submitted on a USB drive or CD sent by express post or registered mail to:

Mail: **Minister for Health**
Suite M1 41
c/- Parliament House
CANBERRA ACT 2600

Subject to the *Administrative Appeals Tribunal Act 1975* (AAT Act), if you are dissatisfied with the decision upon reconsideration by the Minister (or the Minister's delegate), you can apply to the Administrative Appeals Tribunal (AAT) for a review of that decision upon reconsideration.

NOTE: This initial decision remains in effect unless and until it is revoked or revoked and substituted by the Minister (or the Minister's delegate) as a result of a request for reconsideration under section 60 of the Act OR is set aside, varied or remitted by the AAT or is otherwise overturned or stayed.

Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

s47F, s47G(1)(a)

Dear Dr s47F

Notice of decision to grant an authority under subsection 19(5) of the *Therapeutic Goods Act 1989* (Authorised Prescriber Scheme) in relation to:

Product: Lutetium-177 PSMA - - Injection

I refer to your application dated 02 Dec 2022 seeking an authority to supply specified therapeutic goods for use in the treatment of humans, to a specified class of recipients under subsection 19(5) of the *Therapeutic Goods Act 1989* (**the Act**).

Decision

As a delegate of the Secretary of the Department of Health and Aged Care under subsection 19(5) of the Act, I have decided to grant an authority:

- to the specified medical practitioner identified in column 1 of **Schedule 1** to this notice ('the Authorised Prescriber');
- to supply the specified therapeutic goods, or class of goods, identified in column 2 of **Schedule 1** for the indication(s) specified in column 3;
- for supply to a class of recipients (patients) suffering from a life-threatening, or otherwise serious illness or condition.

When supplying the goods, you must comply with:

- the treatment directions (if any) identified in column 4 of **Schedule 1** (subsection 19(7) of the Act and subregulation 12B(3) of the *Therapeutic Goods Regulations 1990* (**the Regulations**) refer); and
- the conditions referred to below.

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Reasons

I grant this authority having considered the information in the application.

I am satisfied that each of the following requirements is met:

- **Class of medical practitioners**
  The Authorised Prescriber is included in the class of medical practitioners being medical practitioners engaged in clinical practice in or outside a hospital (paragraph 19(6)(a) of the Act and subregulation 12B(1) of the Regulations refer);

- **Requirements of subregulation 12B(1B) or 12B(1C)**

The proposed supply of the medicine by the Authorised Prescriber is consistent with the requirements in subregulation 12B(1B) or 12B(1C) of the Regulations relating to the active ingredient (including strength and concentration, as applicable), dosage form, route of administration and indication;

- **Class of recipients**
  The class of recipients (patients) is to consist of persons each of whom is suffering from a life-threatening, or otherwise serious, illness or condition (paragraph 19(6)(b) of the Act and subregulation 12B(2) refers).

Conditions

This authority is granted subject to the following conditions (if any) imposed by me in accordance with subsection 19(5A) of the Act:

The Authorised Prescriber ('you') must only prescribe the specified therapeutic goods or class of goods ('the product') for patients under your immediate care.

If your registration as a medical practitioner is suspended or cancelled, you must notify the TGA within 5 business days of you receiving notification of the suspension or cancellation.

You must obtain informed consent in writing from each patient (or guardian) in relation to the proposed use of the product. Before obtaining consent, you must inform the patient that the product is not in the Australian Register of Therapeutic Goods and has not been evaluated for quality, safety and efficacy in the Australian context.

You must instruct the patient (or guardian) to return any unused product to you or to a pharmacy for destruction.

You must report any suspected adverse reaction to the product to the TGA within 15 calendar days after becoming aware of the reaction.

You must report any fatal or life-threatening adverse reaction to the product to the TGA within 7 calendar days after becoming aware of the reaction. You must follow up with a complete report (if not provided within the 7 calendar day period) within 8 additional calendar days.

You must ensure that other medical practitioners involved in the treatment of a patient's conditions are kept informed of the use of the product and progress to ensure good medicine practice.

Other information

Reporting requirements

Under regulation 47B of the Regulations, you are required to report details of the supply of the therapeutic good to the Secretary on a six monthly basis. The reporting periods are for 1 January to 30 June, and 1 July to 31 December, respectively. Reports must be provided within one calendar month of the reporting period ending. It is preferred the report is provided using the SAS & AP

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Online System, available at https://compliance.health.gov.au/sas/ however a paper form is available from the Authorised Prescriber webpage for exceptional circumstances.

Review rights

Your review rights in relation to this decision are outlined at **Schedule 2** to this notice.
Please contact the Authorised Prescriber team by phone on 02 6289 4632 or email to authorised.prescribers@health.gov.au for further queries regarding this matter.

Period authority is in effect

This authority has effect for the period commencing on the date of this notice until 02 Dec 2027, unless the Secretary (or a delegate) decides to revoke the authority sooner.
Dated 09 Dec 2022

s47F
Delegate of the Secretary
Therapeutic Goods Administration

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Schedule 1:

Details of authority granted under subsection 19(5) of the *Therapeutic Goods Act 1989*

Reference (MAP22-0042732)

Column 1 Authorised Prescriber	Column 2 Specified therapeutic goods (or class of goods)	Column 3 Specified indication(s)	Column 4 Treatment directions (if any)
Dr s47F, s47G(1)(a)	Lutetium-177 PSMA - - Injection 8 Gigabecquerel Injection Intravenous	For the following indication(s): Treatment of metastatic castration-resistant prostate cancer (AP155)	

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Schedule 2:

Request for reconsideration of an initial decision

This decision is a reviewable initial decision under section 60 of the Act. Under section 60, a person whose interests are affected by a 'reviewable' initial decision, can seek reconsideration of the initial decision.

As this document constitutes written notice of the making of an initial decision being given by the Secretary, a request for reconsideration of this initial decision must be given to the Minister in writing within 90 (calendar) days after the initial decision notice is given and be accompanied by any information that you wish to have considered by the Minister. A request for reconsideration given to the Minister outside the statutory 90 day reconsideration period cannot be accepted.

The Minister may either personally undertake a request for reconsideration of an initial decision or delegate this function to an officer of the Department with the appropriate delegation.

Under section 60(3A) of the Act, the Minister (or the Minister's delegate) is not able to consider any information provided after the making of a request for reconsideration of an initial decision unless the information is provided in response to a request from the Minister (or the Minister's delegate), or it is information that indicates that the quality, safety or efficacy of the relevant therapeutic goods is unacceptable.

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Guidelines for requesting reconsideration of an initial decision

Prior to requesting reconsideration of an initial decision, persons affected by an initial decision are advised to refer to the TGA website https://www.tga.gov.au/reconsideration-reviewable-initial-decisions for specific information and detailed guidance for making a request for reconsideration. A request for reconsideration should then be made in writing, signed and dated by the person requesting reconsideration and should include the following:

- a copy of the initial decision notification letter, i.e. this letter (or other evidence of notification);
- identify, and describe with as much specificity as possible, which component(s) of the initial decision should be reconsidered and set out the reasons why reconsideration is requested;
- any information/documentation in support of the request, clearly labelled to correspond with (any or each of) the reasons why reconsideration is requested; and
- an email address nominated for the purposes of receiving correspondence in relation to the request for reconsideration.

All requests for reconsideration should be given to the Minister by email:
Email: **'decision.review@health.gov.au'**
Subject: **"<insert name of person/company making request>** - Request for Reconsideration Under Section 60 of the Therapeutic Goods Act 1989"

Requests for reconsideration that include material which cannot be attached to a single email, may be submitted under multiple, sequentially numbered emails (e.g. "… - Email 1 of 3", "… - Email 2 of 3" etc). All sequentially numbered emails must be given to the Minister on the same date.

Under section 60 of the Act, the decision upon reconsideration by the Minister (or the Minister's delegate) must be to either 'confirm', 'revoke' or 'revoke and substitute' the initial decision. The Minister (or the Minister's delegate) must give notice in writing of the outcome of the decision upon reconsideration to the person whose interests are affected, within 60 (calendar) days after making a

request for reconsideration. If the Minister (or the Minister's delegate) fails to give such notice within 60 days, the Minister (or the Minister's delegate) is deemed to have confirmed the initial decision.

Subject to the Administrative Appeals Tribunal Act 1975 (AAT Act), if you are dissatisfied with the decision upon reconsideration by the Minister (or the Minister's delegate), you can apply to the Administrative Appeals Tribunal (AAT) for a review of that decision upon reconsideration.

NOTE: This initial decision remains in effect unless and until it is revoked or revoked and substituted by the Minister (or the Minister's delegate) as a result of a request for reconsideration under section 60 of the Act OR is set aside, varied or remitted by the AAT or is otherwise overturned or stayed.

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

Dr s47F

Our Reference: MAP23-0044142

Dear Dr s47F

Notice of decision to grant an authority under subsection 19(5) of the *Therapeutic Goods Act 1989* (Authorised Prescriber Scheme) in relation to:

Product: Lutetium-177 PSMA - - Injection

I refer to your application dated 17 Jan 2023 seeking an authority to supply specified therapeutic goods for use in the treatment of humans, to a specified class of recipients under subsection 19(5) of the *Therapeutic Goods Act 1989* (**the Act**).

Decision

As a delegate of the Secretary of the Department of Health and Aged Care under subsection 19(5) of the Act, I have decided to grant an authority:

- to the specified medical practitioner identified in column 1 of **Schedule 1** to this notice ('the Authorised Prescriber');
- to supply the specified therapeutic goods, or class of goods, identified in column 2 of **Schedule 1** for the indication(s) specified in column 3;
- for supply to a class of recipients (patients) suffering from a life-threatening, or otherwise serious illness or condition.

When supplying the goods, you must comply with:

- the treatment directions (if any) identified in column 4 of **Schedule 1** (subsection 19(7) of the Act and subregulation 12B(3) of the *Therapeutic Goods Regulations 1990* (**the Regulations**) refer); and
- the conditions referred to below.

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Reasons

I grant this authority having considered the information in the application.

I am satisfied that each of the following requirements is met:

- **Class of medical practitioners**
  The Authorised Prescriber is included in the class of medical practitioners being medical practitioners engaged in clinical practice in or outside a hospital (paragraph 19(6)(a) of the Act and subregulation 12B(1) of the Regulations refer);

- **Requirements of subregulation 12B(1B) or 12B(1C)**

The proposed supply of the medicine by the Authorised Prescriber is consistent with the requirements in subregulation 12B(1B) or 12B(1C) of the Regulations relating to the active ingredient (including strength and concentration, as applicable), dosage form, route of administration and indication;

- **Class of recipients**
  The class of recipients (patients) is to consist of persons each of whom is suffering from a life-threatening, or otherwise serious, illness or condition (paragraph 19(6)(b) of the Act and subregulation 12B(2) refers).

Conditions

This authority is granted subject to the following conditions (if any) imposed by me in accordance with subsection 19(5A) of the Act:

The Authorised Prescriber ('you') must only prescribe the specified therapeutic goods or class of goods ('the product') for patients under your immediate care.

If your registration as a medical practitioner is suspended or cancelled, you must notify the TGA within 5 business days of you receiving notification of the suspension or cancellation.

You must obtain informed consent in writing from each patient (or guardian) in relation to the proposed use of the product. Before obtaining consent, you must inform the patient that the product is not in the Australian Register of Therapeutic Goods and has not been evaluated for quality, safety and efficacy in the Australian context.

You must instruct the patient (or guardian) to return any unused product to you or to a pharmacy for destruction.

You must report any suspected adverse reaction to the product to the TGA within 15 calendar days after becoming aware of the reaction.

You must report any fatal or life-threatening adverse reaction to the product to the TGA within 7 calendar days after becoming aware of the reaction. You must follow up with a complete report (if not provided within the 7 calendar day period) within 8 additional calendar days.

You must ensure that other medical practitioners involved in the treatment of a patient's conditions are kept informed of the use of the product and progress to ensure good medicine practice.

Other information

Reporting requirements

Under regulation 47B of the Regulations, you are required to report details of the supply of the therapeutic good to the Secretary on a six monthly basis. The reporting periods are for 1 January to 30 June, and 1 July to 31 December, respectively. Reports must be provided within one calendar month of the reporting period ending. It is preferred the report is provided using the SAS & AP

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Online System, available at https://compliance.health.gov.au/sas/ however a paper form is available from the Authorised Prescriber webpage for exceptional circumstances.

Review rights

Your review rights in relation to this decision are outlined at **Schedule 2** to this notice.
Please contact the Authorised Prescriber team by phone on 02 6289 4632 or email to authorised.prescribers@health.gov.au for further queries regarding this matter.

Period authority is in effect

This authority has effect for the period commencing on the date of this notice until 17 Jan 2028, unless the Secretary (or a delegate) decides to revoke the authority sooner.
Dated 24 Jan 2023

s47F
Delegate of the Secretary
Therapeutic Goods Administration

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Schedule 1:

Details of authority granted under subsection 19(5) of the *Therapeutic Goods Act 1989*

Reference (MAP23-0044142)

Column 1 Authorised Prescriber	Column 2 Specified therapeutic goods (or class of goods)	Column 3 Specified indication(s)	Column 4 Treatment directions (if any)
Dr s47F, s47G(1)(a)	Lutetium-177 PSMA - - Injection 8 Gigabecquerel Injection Intravenous	For the following indication(s): AP155-Treatment of metastatic castration resistant prostate cancer	

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Schedule 2:

Request for reconsideration of an initial decision

This decision is a reviewable initial decision under section 60 of the Act. Under section 60, a person whose interests are affected by a 'reviewable' initial decision, can seek reconsideration of the initial decision.

As this document constitutes written notice of the making of an initial decision being given by the Secretary, a request for reconsideration of this initial decision must be given to the Minister in writing within 90 (calendar) days after the initial decision notice is given and be accompanied by any information that you wish to have considered by the Minister. A request for reconsideration given to the Minister outside the statutory 90 day reconsideration period cannot be accepted.

The Minister may either personally undertake a request for reconsideration of an initial decision or delegate this function to an officer of the Department with the appropriate delegation.

Under section 60(3A) of the Act, the Minister (or the Minister's delegate) is not able to consider any information provided after the making of a request for reconsideration of an initial decision unless the information is provided in response to a request from the Minister (or the Minister's delegate), or it is information that indicates that the quality, safety or efficacy of the relevant therapeutic goods is unacceptable.

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Guidelines for requesting reconsideration of an initial decision

Prior to requesting reconsideration of an initial decision, persons affected by an initial decision are advised to refer to the TGA website https://www.tga.gov.au/reconsideration-reviewable-initial-decisions for specific information and detailed guidance for making a request for reconsideration. A request for reconsideration should then be made in writing, signed and dated by the person requesting reconsideration and should include the following:

- a copy of the initial decision notification letter, i.e. this letter (or other evidence of notification);
- identify, and describe with as much specificity as possible, which component(s) of the initial decision should be reconsidered and set out the reasons why reconsideration is requested;
- any information/documentation in support of the request, clearly labelled to correspond with (any or each of) the reasons why reconsideration is requested; and
- an email address nominated for the purposes of receiving correspondence in relation to the request for reconsideration.

All requests for reconsideration should be given to the Minister by email:
Email: **'decision.review@health.gov.au'**
Subject: **"<insert name of person/company making request>** - Request for Reconsideration Under Section 60 of the Therapeutic Goods Act 1989"

Requests for reconsideration that include material which cannot be attached to a single email, may be submitted under multiple, sequentially numbered emails (e.g. "… - Email 1 of 3", "… - Email 2 of 3" etc). All sequentially numbered emails must be given to the Minister on the same date.

Under section 60 of the Act, the decision upon reconsideration by the Minister (or the Minister's delegate) must be to either 'confirm', 'revoke' or 'revoke and substitute' the initial decision. The Minister (or the Minister's delegate) must give notice in writing of the outcome of the decision upon reconsideration to the person whose interests are affected, within 60 (calendar) days after making a

request for reconsideration. If the Minister (or the Minister's delegate) fails to give such notice within 60 days, the Minister (or the Minister's delegate) is deemed to have confirmed the initial decision.

Subject to the Administrative Appeals Tribunal Act 1975 (AAT Act), if you are dissatisfied with the decision upon reconsideration by the Minister (or the Minister's delegate), you can apply to the Administrative Appeals Tribunal (AAT) for a review of that decision upon reconsideration.

NOTE: This initial decision remains in effect unless and until it is revoked or revoked and substituted by the Minister (or the Minister's delegate) as a result of a request for reconsideration under section 60 of the Act OR is set aside, varied or remitted by the AAT or is otherwise overturned or stayed.

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Dr s47F

Our Reference: MAP23-0059724

Dear Dr s47F

Notice of decision to grant an authority under subsection 19(5) of the *Therapeutic Goods Act 1989* (Authorised Prescriber Scheme) in relation to:

Product: Lutetium-177 Prostate Specific Membrane Antigen (PSMA) - Injection

I refer to your application dated 09 Nov 2023 seeking an authority to supply specified therapeutic goods for use in the treatment of humans, to a specified class of recipients under subsection 19(5) of the *Therapeutic Goods Act 1989* (**the Act**).

Decision

As a delegate of the Secretary of the Department of Health and Aged Care under subsection 19(5) of the Act, I have decided to grant an authority:

- to the specified medical practitioner identified in column 1 of **Schedule 1** to this notice ('the Authorised Prescriber');
- to supply the specified therapeutic goods, or class of goods, identified in column 2 of **Schedule 1** for the indication(s) specified in column 3;
- for supply to a class of recipients (patients) suffering from a life-threatening, or otherwise serious illness or condition.

When supplying the goods, you must comply with:

- the treatment directions (if any) identified in column 4 of **Schedule 1** (subsection 19(7) of the Act and subregulation 12B(3) of the *Therapeutic Goods Regulations 1990* (**the Regulations**) refer); and
- the conditions referred to below.

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Reasons

I grant this authority having considered the information in the application.

I am satisfied that each of the following requirements is met:

- **Class of medical practitioners**
  The Authorised Prescriber is included in the class of medical practitioners being medical practitioners engaged in clinical practice in or outside a hospital (paragraph 19(6)(a) of the Act and subregulation 12B(1) of the Regulations refer);

- **Requirements of subregulation 12B(1B) or 12B(1C)**
  The proposed supply of the medicine by the Authorised Prescriber is consistent with the requirements in subregulation 12B(1B) or 12B(1C) of the Regulations relating to the active

PO Box 100 Woden ACT 2606 ABN 40 939 406 804
Phone: 1800 020 653 Fax: 02 6203 1605 Email: info@tga.gov.au
https://www.tga.gov.au

TGA Health Safety Regulation

ingredient (including strength and concentration, as applicable), dosage form, route of administration and indication;

- **Class of recipients**
  The class of recipients (patients) is to consist of persons each of whom is suffering from a life-threatening, or otherwise serious, illness or condition (paragraph 19(6)(b) of the Act and subregulation 12B(2) refers).

Conditions

This authority is granted subject to the following conditions (if any) imposed by me in accordance with subsection 19(5A) of the Act:

1. The Authorised Prescriber ('you') must only prescribe the specified therapeutic goods or class of goods ('the product') for patients under your immediate care in the manner described in the approval
2. You and the patient (or the person with the legal authority to consent to the treatment on behalf of the patient) must accept responsibility for the outcome of the use of the product.
3. You must obtain informed consent in writing from each patient (or the person with the legal authority to consent to the treatment on behalf of the patient) in relation to the proposed use of the product in accordance with good medical practice.
4. You must ensure that other medical practitioners involved in the treatment of a patient's conditions are kept informed of the use of the product adhering to the relevant standards of good medical practice as set out by your relevant professional regulating body.
5. You must report any suspected adverse reaction to the product to the TGA within 15 calendar days after becoming aware of the reaction. The preferred reporting route is via the online portal https://aems.tga.gov.au;
6. If your registration as a medical practitioner is suspended or cancelled, you must notify the TGA within 5 business days of you receiving notification of the suspension or cancellation.

Please note that it is the responsibility of the approval holder to arrange for the importation into, exportation from, or the supply in Australia of the specified medicine and to provide evidence of this approval to the person or persons with whom the importation into, the exportation from, or the supply in Australia is arranged.

Additional restrictions may be placed on the importation of therapeutic goods as outlined below. You will need to check with the relevant agencies to obtain permission if required.

- *Customs (Prohibited Imports) Regulations 1956* - import permits and licences are required for substances controlled under these Regulations. Contact the Office of Drug Control at NCS@health.gov.au for further information.
- *Biosecurity Act 2015* - permission may be required prior to importing any material of biological origin (human, animal, plant or microbial). Contact the Department of Agriculture, Water and the Environment at imports@agriculture.gov.au for information.
- *Environment Protection and Biodiversity Conservation Act 1999* - permission may be required prior to importing endangered species. Contact the Department of Agriculture, Water and the Environment at wps@awe.gov.au for information.
- *Gene Technology Act 2000* – permission may be required prior to importing genetically modified organisms. Email the Office of the Gene Technology Regulator (OGTR) at ogtr@health.gov.au for information.

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

PO Box 100 Woden ACT 2606 ABN 40 939 406 804
Phone: 1800 020 653 Fax: 02 6203 1605 Email: info@tga.gov.au
https://www.tga.gov.au

State and territory requirements - contact the relevant state/territory health department for further information.

Other information

Reporting requirements
Under regulation 47B of the Regulations, you are required to report details of the supply of the therapeutic good to the Secretary on a six monthly basis. The reporting periods are for 1 January to 30 June, and 1 July to 31 December, respectively. Reports must be provided within one calendar month of the reporting period ending. It is preferred the report is provided using the SAS & AP Online System, available at https://compliance.health.gov.au/sas/ however a paper form is available from the Authorised Prescriber webpage for exceptional circumstances.
Please note, it is an offence to supply false or misleading information to a government agency.

Review rights
Please contact the Authorised Prescriber team by email (authorised.prescribers@health.gov.au) for further queries regarding this matter.

Period authority is in effect
This authority has effect for the period commencing on the date of this notice until 09 Nov 2028, unless the Secretary (or a delegate) decides to revoke the authority sooner.
Dated 13 Nov 2023

s47F
Delegate of the Secretary
Therapeutic Goods Administration

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

PO Box 100 Woden ACT 2606 ABN 40 939 406 804
Phone: 1800 020 653 Fax: 02 6203 1605 Email: info@tga.gov.au
https://www.tga.gov.au

TGA Health Safety Regulation

Schedule 1:

Details of authority granted under subsection 19(5) of the *Therapeutic Goods Act 1989*

Reference (MAP23-0059724)

Column 1 Authorised Prescriber	Column 2 Specified therapeutic goods (or class of goods)	Column 3 Specified indication(s)	Column 4 Treatment directions (if any)
Dr s47F, s47G(1)(a)	Lutetium-177 Prostate Specific Membrane Antigen (PSMA) - Injection 8 Gigabecquerel Injection Intravenous	For the following indication(s): AP155-Treatment of metastatic castration resistant prostate cancer	

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

PO Box 100 Woden ACT 2606 ABN 40 939 406 804
Phone: 1800 020 653 Fax: 02 6203 1605 Email: info@tga.gov.au
https://www.tga.gov.au

Request for reconsideration of an initial decision

This decision is a reviewable initial decision under section 60 of the Act. Under section 60, a person whose interests are affected by a 'reviewable' initial decision, can seek reconsideration of the initial decision.

As this document constitutes written notice of the making of an initial decision being given by the Secretary, a request for reconsideration of this initial decision must be given to the Minister in writing within 90 (calendar) days after the initial decision notice is given and be accompanied by any information that you wish to have considered by the Minister. A request for reconsideration given to the Minister outside the statutory 90 day reconsideration period cannot be accepted.

The Minister may either personally undertake a request for reconsideration of an initial decision or delegate this function to an officer of the Department with the appropriate delegation.

Under section 60(3A) of the Act, the Minister (or the Minister's delegate) is not able to consider any information provided after the making of a request for reconsideration of an initial decision unless the information is provided in response to a request from the Minister (or the Minister's delegate), or it is information that indicates that the quality, safety or efficacy of the relevant therapeutic goods is unacceptable.

Guidelines for requesting reconsideration of an initial decision

Prior to requesting reconsideration of an initial decision, persons affected by an initial decision are advised to refer to the TGA website <https://www.tga.gov.au/resources/resource/guidance/guidance-requesting-reconsideration-initial-decision> for specific information and detailed guidance for making a request for reconsideration. A request for reconsideration should then be made in writing, signed and dated by the person requesting reconsideration and should include the following:

- a copy of the initial decision notification letter, i.e. this letter (or other evidence of notification);
- identify, and describe with as much specificity as possible, which component(s) of the initial decision should be reconsidered and set out the reasons why reconsideration is requested;
- any information/documentation in support of the request, clearly labelled to correspond with (any or each of) the reasons why reconsideration is requested; and
- an email address nominated for the purposes of receiving correspondence in relation to the request for reconsideration.

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

All requests for reconsideration should be given to the Minister by email:

Email: **'decision.review@health.gov.au'**

Subject: **"<insert name of person/company making request>** - Request for Reconsideration Under Section 60 of the Therapeutic Goods Act 1989"

Requests for reconsideration that include material which cannot be attached to a single email, may be submitted under multiple, sequentially numbered emails (e.g. "... - Email 1 of 3", "... - Email 2 of 3" etc). All sequentially numbered emails must be given to the Minister on the same date.

Under section 60 of the Act, the decision upon reconsideration by the Minister (or the Minister's delegate) must be to either 'confirm', 'revoke' or 'revoke and substitute' the initial decision. The

PO Box 100 Woden ACT 2606 ABN 40 939 406 804
Phone: 1800 020 653 Fax: 02 6203 1605 Email: info@tga.gov.au
https://www.tga.gov.au

Minister (or the Minister's delegate) must give notice in writing of the outcome of the decision upon reconsideration to the person whose interests are affected, within 60 (calendar) days after making a request for reconsideration. If the Minister (or the Minister's delegate) fails to give such notice within 60 days, the Minister (or the Minister's delegate) is deemed to have confirmed the initial decision.

Subject to the Administrative Appeals Tribunal Act 1975 (AAT Act), if you are dissatisfied with the decision upon reconsideration by the Minister (or the Minister's delegate), you can apply to the Administrative Appeals Tribunal (AAT) for a review of that decision upon reconsideration.

NOTE: This initial decision remains in effect unless and until it is revoked or revoked and substituted by the Minister (or the Minister's delegate) as a result of a request for reconsideration under section 60 of the Act OR is set aside, varied or remitted by the AAT or is otherwise overturned or stayed.

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

PO Box 100 Woden ACT 2606 ABN 40 939 406 804
Phone: 1800 020 653 Fax: 02 6203 1605 Email: info@tga.gov.au
https://www.tga.gov.au

Authorised Prescriber	Product Profile	Product Presentation	Number of New Patients	Number of Prescription or Devices
MAP22-0042732	Lutetium-177 Prostate Specific Membrane Antigen (PSMA)	Lutetium-177 Prostate Specific Membrane Antigen (PSMA)	0	0
MAP22-0036485	Regadenoson	Regadenoson	0	0

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Authorised Prescriber	Product Profile	Product Presentation	Number of New Patients	Number of Prescription or Devices
MAP23-0061743	Regadenoson	Regadenoson	1	1
MAP22-0042732	Lutetium-177 Prostate Specific Membrane Antigen (PSMA)	Lutetium-177 Prostate Specific Membrane Antigen (PSMA)	7	9
MAP24-0074698	Lutetium-177 Octreotate (177 Lu-DOTATATE)	Lutetium-177 Octreotate (177 Lu-DOTATATE)	0	0
MAP23-0053343	Regadenoson	Regadenoson	0	0

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Authorised Prescriber	Product Profile	Product Presentation	Number of New Patients	Number of Prescription or Devices
MAP23-0053343	Regadenoson	Regadenoson	0	0
MAP22-0042732	Lutetium-177 Prostate Specific Membrane Antigen (PSMA)	Lutetium-177 Prostate Specific Membrane Antigen (PSMA)	1	1
MAP23-0061743	Regadenoson	Regadenoson	0	0

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Authorised Prescriber	Product Profile	Product Presentation	Number of New Patients	Number of Prescription or Devices
MAP22-0042732	Lutetium-177 Prostate Specific Membrane Antigen (PSMA)	Lutetium-177 Prostate Specific Membrane Antigen (PSMA)	0	0
MAP23-0061743	Regadenoson	Regadenoson	0	0
MAP24-0074698	Lutetium-177 Octreotate (177 Lu-DOTATATE)	Lutetium-177 Octreotate (177 Lu-DOTATATE)	1	1

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Authorised Prescriber	Product Profile	Product Presentation	Number of New Patients	Number of Prescription or Devices
MAP24-0065699	F18\18F-DCFPyL Prostate Specific Membrane Antigen (PSMA)	F18\18F-DCFPyL Prostate Specific Membrane Antigen (PSMA)	81	81
MAP23-0059724	Lutetium-177 Prostate Specific Membrane Antigen (PSMA)	Lutetium-177 Prostate Specific Membrane Antigen (PSMA)	66	113

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Authorised Prescriber	Product Profile	Product Presentation	Number of New Patients	Number of Prescription or Devices
MAP21-0024486	Lutetium-177 Prostate Specific Membrane Antigen (PSMA)	Lutetium-177 Prostate Specific Membrane Antigen (PSMA)	24	82
MAP23-0059724	Lutetium-177 Prostate Specific Membrane Antigen (PSMA)	Lutetium-177 Prostate Specific Membrane Antigen (PSMA)	24	82

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care

Authorised Prescriber	Product Profile	Product Presentation	Number of New Patients	Number of Prescription or Devices
MAP24-0065699	F18\18F-DCFPyL Prostate Specific Membrane Antigen (PSMA)	F18\18F-DCFPyL Prostate Specific Membrane Antigen (PSMA)	100	104
MAP23-0059724	Lutetium-177 Prostate Specific Membrane Antigen (PSMA)	Lutetium-177 Prostate Specific Membrane Antigen (PSMA)	64	295

This Document Has Been Released Under The Freedom Of Information Act 1982 By The Department Of Health And Aged Care