



## General use items

Pre-consultation paper – 27 June 2024  
workshop with private health insurance  
stakeholders

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## Overview

On 1 May 2024, the Minister of Health and Aged Care announced that general use items (GUI) would be retained in Part D of the Prescribed List (PL). This decision follows continuous feedback from multiple stakeholders that removing the GUIs from the PL would have negative clinical implications and potential adverse outcomes for patients.

The announcement comes two years after the initial planned removal of the GUIs from the PL, and a year after insurers and hospitals were requested to negotiate alternative funding arrangements.

We acknowledge the concerns of private health insurers that the announcement about retaining GUI on the PL represent. The department is undertaking further consultation and engagement to identify ways in which these concerns might be addressed – both regulatory and non-regulatory.

## What we invite you to do

We ask that you provide us with practical suggestions about ways to increase the integrity of the settings of the PL as well as mechanisms to reduce increased growth in usage of GUIs per episode of care and the resulting increased growth in expenditure (i.e. without any clinical need).

In considering your input to this matter we ask that you provide as much detail and evidence as possible. Please ensure your suggestions remain in the context of the Prescribed List and are reasonable, pragmatic and within the authority of the department.

## Questions

At the workshop, we would like to discuss your answers to the following questions.

### Integrity

1. What do you see are the key areas of concern for the integrity of the PL settings in the context of the GUIs?
2. If you were to consider prioritisation of these, what would that look like?
3. What are the potential system based-actions (i.e. not fixing of individual errors) that could be taken, by who and when?
4. How would you suggest the success of these actions are measured?
5. What are the likely consequences – positive/negative and who would they effect?

### Utilisation and growth in expenditure

6. What sub-categories of GUIs on the PL represent the key areas of growth in utilisation per episode of care and therefore increase in benefit expenditure?
7. Are there specific procedures that represent higher growth in utilisation?
8. If there are concerns that the growth in use is not related to clinical need, how is this determined/measured? Who can validate this?
9. What system-based mechanisms are either in place or need to be put in place to address this problem?
  - a. Would these mechanisms be different if there was a demonstrated clinical need?
10. How would you suggest the success of these actions are measured?
11. What are the likely consequences – positive/negative and who would they effect?

## Other matters

12. Are there other areas of concern with the retention of GUIs on the PL that need to be considered?

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# Workshop on general use items integrity, utilisation and growth in expenditure

## Meeting Agenda

**Date:** Thursday, 27 June 2024  
**Time:** 10:00 am to 1:00 pm  
**Location:** Department of Health and Aged Care (Sirius Building 23 Furzer Street, Woden Australian Capital Territory 2606)  
**Email:** prosthesesreform@health.gov.au

#	Agenda Item	Lead
1	<ul style="list-style-type: none"><li>Acknowledgement of Country</li><li>Welcome and opening of the meeting</li><li>Introductions</li></ul>	Department <ul style="list-style-type: none"><li>Andrew Rintoul</li></ul>
2	<ul style="list-style-type: none"><li>Discussion - Integrity</li></ul>	Department <ul style="list-style-type: none"><li>Andrew Rintoul</li></ul>
3	<ul style="list-style-type: none"><li>Discussion – Utilisation and growth in expenditure</li></ul>	Department <ul style="list-style-type: none"><li>Andrew Rintoul</li></ul>
4	<ul style="list-style-type: none"><li>Questions – Follow up from the department</li></ul>	Department <ul style="list-style-type: none"><li>Andrew Rintoul</li></ul>
6	<ul style="list-style-type: none"><li>Other matters</li></ul>	Private Health Association

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**From:** [Ben Harris](#)  
**To:** s22  
**Subject:** GUI letter attachment 9 May 2024  
**Date:** Thursday, 27 June 2024 12:46:26 PM  
**Attachments:** [20240509 PHA Dr Rachel David to Minister Butler re GUI on PL attachment.pdf](#)

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**Ben Harris**

DIRECTOR OF POLICY AND RESEARCH

M: s47F | E: s47F@pha.org.au

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## General Use items controls and tweaks to the list

DRAFT AS AT NOON THU 2 MAY 2024

PHA's major concern is volume and cost being added with no demonstrable clinical benefits. For example, there was a 12.9% volume growth in GUI in 2017/18 on flat surgery volumes.

### Recommended overall rules

- Price/volume agreements
  - If the total use of items under each subcategory increases by more than 10% in any year (adjusted for any increases in surgical volume), the price of all items under that code should be reduced by 10% (rounded up to the nearest dollar).
- Ensure no out of pocket costs for consumers as a condition of listing. This is likely to require the price to hospitals not to exceed the PL price.
- Any price increases (i.e. through amendment applications) to demonstrate a public interest case, including the clinical and economic benefits. These public interest cases should be published by the Minister each PL cycle.
- Hospitals provide feedback on the costs of medical devices and standard usage patterns to their medical staff (as previously offered by hospital groups).
- Where hospitals use general use items at a significantly higher rate than their peer group (for example, over 20% to 50% higher than the average depending on distribution), payment will be provided in full only where the treating doctors certify that the unusual use is reasonable and necessary, otherwise a 120% to 150% expenditure cap will apply.
- Remove suffices which do not impact on the patient outcome. These would include price reductions where there is no consumer benefit from device characteristics (we have a list to consider, see below)

### Fix mistakes on the list

- Address error in pricing and all adhesion barriers with the same ARTG back to public price (reduce spend by \$1.018m)
- Use the Surgiflo price 6ml for Floseal, Purastat 5mls as there's no difference in price at the higher volume between Floseal and Surgiflo (reducing spend by \$0.620m)
- Hemoblast VB002 reduced to same price as Floseal, Surgiflo (reducing spend by \$0.225m)
- Applicators (03.05.05.05 - Accessory Extender) removed, as they should be incorporated into the device as per public prices (reducing spend by \$0.022m)

- Move ET082 PureRegen Gel Sinus from adhesion barriers to nasal code (no price impact)
- Remove internal adhesive applicators (03.08.02.04 - Adhesive Accessory) as they should be included in device cost as per public prices (reduce spend by \$1.792m)
- Add conditions of use for Tisseal etc to vascular and dura consistent with IFU
- Remove Evicel as it is a listed medicine, not a device (not eligible)
- Remove ET065 as it is a suture and not eligible
- Remove ET066 as not eligible (reduce spend by \$1.081m)
- Tristapler MI287 and GIA stapler AS209 repriced to the sum of the component parts (reduce spend by \$2.004m)
- Remove CoreKnot, these are surgical instruments (DE606, DE609)
- Remove anomaly where larger sponges receive much higher remuneration, change to per cm for all sizes (reduce spend by \$0.083m)
- Reprice all liquid repair sealants to the highest volume price, rather than paying more for the smaller sizes.
- Place condition on use for all liquid repair sealants to dura, as per IFUs
- ER279 OverStitch™ Endoscopic Suturing System repriced to comparator FQ002

## Recommended price reviews

- Remove premium for powered stapler as no HTA assessment was undertaken (reduce spend by \$1.129m)
- Remove premium for endoscopic suffice for staplers as no clear difference in performance in most instances (reduce spend by \$12.759m).
- Reprice KI010 to \$90 as it is readily available at that price ([here](#))
- Reduce price for 03.08.04.04 - Staplers, Non-bone with Disposable Applier to the same as 03.08.04.02 – Staplers. There is no justification for the premium.

## Suggested changes to improve integrity

- Remove capital items for infusion pumps and increase cassette cost to compensate (no net financial impact).
  - Remove 03.02.03 - Infusion Pumps, Battery Powered
  - The price of the 03.02.05.02 - Administration Cassettes would need to increase from \$26 to \$51 to compensate for these items coming off
- Use a single price for pliable patches to remove incentives for larger sizes (no net financial impact)
- Use a per gram price for haemostatic power to remove incentives for larger sizes (no net financial impact)
- Use a single price for absorbable sponges to remove incentives for larger sizes (no net financial impact)

- Consider merging all the items under 10.09.01 - Percutaneous Catheters, Single Lumen, removing all suffices and averaging the price (no net financial impact)
- Consider merging all the items under 10.09.02 - Percutaneous Catheters, removing all suffices and averaging the price (no net financial impact)

## Suffices to remove

While professional advice is required, these suffices appear to be based on the characteristics of the device rather than an effect on patient care.

For example, stapler reloads are similar regardless of the type of stapler, there is unlikely to be a need for a suffix and additional payment.

03.02.02 - Infusion Pumps, Balloon Based	03.02.02.01 - Fixed Flow Rate	Bolus
03.05.03 - Sponges	03.05.03.01 - Absorbable $\leq 75\text{cm}^2$	Anatomically Conforming
03.05.03 - Sponges	03.05.03.01 - Absorbable $\leq 75\text{cm}^2$	Low Antigenicity
03.05.03 - Sponges	03.05.03.02 - Absorbable $> 75\text{cm}^2$	Low Antigenicity
03.05.04 - Pliable Patches	03.05.04.01 - Absorbable $\leq 50\text{cm}^2$	Antimicrobial, Low Antigenicity
03.05.05 - Matrix	03.05.05.02 - Liquid $> 6\text{ml}$	Complete Biomaterial
03.08.03 - Ligating Devices	03.08.03.01 - Clips	Polymeric Non-resorbable
03.08.02 - Internal Adhesives	03.08.02.02 - Adhesive $> 2\text{-}5\text{ml}$	Biological
03.08.02 - Internal Adhesives	03.08.02.02 - Adhesive $> 2\text{-}5\text{ml}$	Synthetic
03.08.03 - Ligating Devices	03.08.03.03 - Clips with Disposable Applier	Laparoscopic



03.08.03 - Ligating Devices	03.08.03.03 - Clips with Disposable Applier	Open
03.08.04 - Staples & Tackers	03.08.04.01 - Staples, Non-bone (Reload)	Curved
03.08.04 - Staples & Tackers	03.08.04.01 - Staples, Non-bone (Reload)	Endoscopic, Articulating/Rotulating

### Note on figures used

- Financial outcomes quoted are based on 2021-22 volumes and prices as at 1 March 2023 (not the November list).
  - This list was first done prior to notification of the 1 November 2023 price cuts.

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**From:** [Ben Harris](#)  
**To:** s22  
**Subject:** Re: Meeting/workshop request on general use items [SEC=OFFICIAL]  
**Date:** Wednesday, 15 May 2024 12:34:16 PM  
**Attachments:** [image001.png](#)  
[image002.jpg](#)  
[image003.png](#)

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We will come to Woden.

**Ben Harris**

DIRECTOR OF POLICY AND RESEARCH

T: s47F | M: s47F | E: s47F @pha.org.au

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On 15 May 2024, at 12:30 PM, s22  
 <s22@health.gov.au> wrote:

Hi Ben,

Apologies, I just wanted to check if yourself, s47F and s47F would be attending face-to-face or over Webex?

Thank you!

Warm Regards,

s22

**Executive Assistant to Andrew Rintoul | Assistant Secretary  
 Prostheses List Reform Taskforce**

<image001.png>

Technology Assessment and Access Division  
 Australian Government Department of Health and Aged Care

T: 02 6289 s22

E: s22@health.gov.au

Location: Sirius Building 9.N

PO Box 9848, Canberra ACT 2601, Australia

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**From:** Ben Harris <s47F@pha.org.au>

**Sent:** Monday, May 13, 2024 11:03 AM

**To:** s22@Health.gov.au

**Subject:** RE: Meeting/workshop request on general use items [SEC=OFFICIAL]

Done. Can you please send the invite as you will need to do a room booking.

For s47F and myself,

Thanks

Ben

**Ben Harris**

DIRECTOR OF POLICY AND RESEARCH

M: s47F | E: s47F@pha.org.au

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**From:** s22@Health.gov.au

**Sent:** Monday, May 13, 2024 10:41 AM

**To:** Ben Harris <s47F@pha.org.au>

**Subject:** RE: Meeting/workshop request on general use items [SEC=OFFICIAL]

Good morning Ben,

Can we lock in Thursday 27 June? That would be great!

Just for clarification, are you sending the invite or is this something you would prefer us to do on our end?

Thank you

Warm Regards,

s22

**Executive Assistant to Andrew Rintoul | Assistant Secretary  
Prostheses List Reform Taskforce**

<image001.png>

Technology Assessment and Access Division  
Australian Government Department of Health and Aged Care

T: 02 6289 s22

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Location: Sirius Building 9.N

PO Box 9848, Canberra ACT 2601, Australia

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**From:** Ben Harris <s47F@pha.org.au>

**Sent:** Friday, May 10, 2024 10:57 AM

**To:** s22@Health.gov.au

**Subject:** FW: Meeting/workshop request on general use items [SEC=OFFICIAL]

Hi s22,

s47F and I would attend, we have the technical expertise.

These dates would suit:

Wed 5 June (pm)

Thu 6

Mon 17

Wed 19

Thu 20

Mon 24

Thu 27  
 Hope one of these works,  
 Thanks  
 Ben

### Ben Harris

DIRECTOR OF POLICY AND RESEARCH

M: s47F | E: s47F @pha.org.au

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**From:** s22 @Health.gov.au

**Sent:** Friday, May 10, 2024 10:07 AM

**To:** Ben Harris s47F @pha.org.au; Rachel David

<s47F @pha.org.au>; s47F s47F

**Subject:** RE: Meeting/workshop request on general use items [SEC=OFFICIAL]

Good morning Ben, Rachel, s47F and s47F,

Happy Friday and I hope you have a relaxing weekend ahead of you!

I was wondering if you would be able to give me a list of times that work for you throughout June. Unfortunately, the workshop won't be able to happen before then.

If you can send me a list, that would be great. I will then continue to coordinate internally with the PLRT team to find a time suitable.

Thank you and I look forward to hearing from you all.

Warm Regards,

s22

**Executive Assistant to Andrew Rintoul | Assistant Secretary  
 Prostheses List Reform Taskforce**

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Technology Assessment and Access Division  
 Australian Government Department of Health and Aged Care

T: 02 6289 s22

E: s22 @health.gov.au

Location: Sirius Building 9.N

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**From:** Ben Harris <s47F @pha.org.au>

**Sent:** Thursday, May 9, 2024 4:46 PM

**To:** RINTOUL, Andrew <s22 @health.gov.au>

**Cc:** s22 @health.gov.au; s22

@Health.gov.au; s22

@health.gov.au; s47F; s47F

; Rachel David <s47F @pha.org.au>;

s22 @Health.gov.au

**Subject:** RE: Meeting/workshop request on general use items [SEC=OFFICIAL]

Thanks Andrew

**Ben Harris**

DIRECTOR OF POLICY AND RESEARCH

M: s47F | E: s47F @pha.org.au

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<image002.jpg>



**From:** RINTOUL, Andrew <s22 @health.gov.au>

**Sent:** Thursday, May 9, 2024 4:35 PM

**To:** Ben Harris <s47F @pha.org.au>

**Cc:** s22 <@health.gov.au>; s22

<@Health.gov.au>; s22

<@health.gov.au>; s47F s47F

; Rachel David <s47F @pha.org.au>;

s22 <@Health.gov.au>

**Subject:** RE: Meeting/workshop request on general use items [SEC=OFFICIAL]

Hi Ben,

I'll ask s22 to coordinate internally and come back to you with a range of times to hold the meeting.

Kind regards

Andrew

**Andrew Rintoul**

Assistant Secretary

<image003.png>

Protheses List Reform Taskforce | Technology Assessment and Access Division

Australian Government Department of Health and Aged Care

T: +61 2 6289 s22 | M: s22 E: s22 @health.gov.au

Location: Sirius 9.N.101

PO Box 9848, Canberra ACT 2601, Australia

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**From:** Ben Harris <s47F @pha.org.au>

**Sent:** Wednesday, May 8, 2024 5:12 PM

**To:** RINTOUL, Andrew <s22 @health.gov.au>

**Cc:** s22 <@health.gov.au>; s22

<@Health.gov.au>; s22

<@health.gov.au>; s47F s47F

; Rachel David <s47F @pha.org.au>

**Subject:** Meeting/workshop request on general use items

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Andrew,

Rachel and I met with s47F and s47F on Friday on general use items on the PL. They have encouraged us to engage with you on our list of errors, integrity issues and consumer protection measures sent last week.

I ask for an extended meeting/workshop with you and your staff on the 40 issues

we have raised with general use items. I recognise that other than s22 many of your staff have not been around long enough to have had exposure to the general use item history – in particular, the EY report and the department’s report on general use items. We have the advantage of the history and the data from funds to add to the repository of knowledge the department has collected over the years, plus the expertise of former device company staff who will be able to help the department come to decisions on how to proceed with protecting consumers’ interests.

We propose going through the technical suggestions, where they have come from (eg the EY report), and why we are recommending what we are recommending (eg using the Hereco framework for regrouping). Our line-by-line examination of the general use category as part of the investment we have made while looking for a solution to general use items should be of value to the taskforce.

I think we could get it done in three hours, with me, s47F and s47F going through the list of recommendations to inform your decisions going forward.

Let me know when would suit you and your team,

Thanks

Ben

**Ben Harris**

DIRECTOR OF POLICY AND RESEARCH

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[<image002.jpg>](#)



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**From:** s47F  
**To:** s22  
**Subject:** RE: Meeting/workshop request on general use items [SEC=OFFICIAL]  
**Date:** Friday, 10 May 2024 4:00:58 PM  
**Attachments:** [image001.png](#)  
[image002.png](#)  
[image003.png](#)  
[image004.png](#)

Oh, that's great, thanks and sorry for the double-up. You've saved me some time.

s47F

**From:** s22 @Health.gov.au>  
**Sent:** Friday, May 10, 2024 3:59 PM  
**To:** s47F @pha.org.au>  
**Subject:** RE: Meeting/workshop request on general use items [SEC=OFFICIAL]

Good morning s47F,

Thank you for your reply, I appreciate it! However, Ben has already provided days that work for the three attendees.

Thank you again!

Warm Regards,

s22

**Executive Assistant to Andrew Rintoul | Assistant Secretary  
 Prostheses List Reform Taskforce**

Technology Assessment and Access Division  
 Australian Government Department of Health and Aged Care

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E: s22 @health.gov.au

Location: Sirius Building 9.N

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**From:** s47F @pha.org.au>

**Sent:** Friday, May 10, 2024 3:46 PM

**To:** s22 @Health.gov.au>

**Subject:** FW: Meeting/workshop request on general use items [SEC=OFFICIAL]

Hi s22 just touching base to let you know that I'll coordinate some dates at this end and get them to you early next week.

s47F

EXECUTIVE ASSISTANT to CEO

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