From: s 47E(d)
To: s47F
Subject: RE: Prescribed List - Condition on billing codes for surgical guides and biomodels [SEC=OFFICIAL]
Date: Tuesday, 17 October 2023 12:39:31 PM
Attachments: image008.png
image009.png
image011.png
image012.png
image001.png

Hi s47F

The condition is that the private health insurers are not required to pay benefits for any more than 3 surgical guides and 3 biomodels per procedure.

If the clinician uses 4 surgical guides or 4 biomodels, the private health insurer is only required to pay benefits for 3 of each. What happens with regard to reimbursement for any further surgical guides or biomodels is a matter of negotiation between the hospital (on behalf of the patient) and the insurer.

Kind regards

Prostheses List Administration Section
Prostheses List Reforms Task Force
Technology Assessment and Access Division | Health Resourcing Group
Australian Government Department of Health and Aged Care
PO Box 9848, Canberra ACT 2601, Australia

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From: s47F @klsmartin.com>
Sent: Tuesday, 17 October 2023 12:02 PM
To: s 47E(d) @health.gov.au>
Subject: RE: Prescribed List - Condition on billing codes for surgical guides and biomodels [SEC=OFFICIAL]

Hi,
Thank you, that does explain the situation. I'm sure you understand the concern and volume of enquiries we are receiving from surgeons during this time.

I also need to seek clarity on this statement; "Clinicians can use more than 3 devices per procedure, but the patient's insurer might need to be consulted on reimbursement for the additional devices."

For complex orthognathic surgery, sometimes 4 patient specific implants are clinically necessary, for which a corresponding surgical guide is essential for implantation by guiding the predrilling of screw holes and performing the virtually planned osteotomies. A restriction of 3 guides effectively acts as an implant restriction as the guide is essential for the implant.

What is the Depts advice on this matter? Are the insurers obligated to reimburse the 4th guide as it directly relates to a specific implant as per listing criteria?
Does "the patient's insurer might need to be consulted on reimbursement for the additional devices" mean the insurer needs to be informed or that approval needs to be formally sought?

Example:

s 47F

We have a number of surgeries already planned and manufactured that fall into this category so if you could advise ASAP, that would be great as we are seeking to minimise the impact to surgeons and patients.

Best Regards,

s47F
s 47F
Craniomaxillofacial Implants

KLS Martin Australia Pty Limited

23/2-6 Chaplin Drive
Lane Cove West NSW 2066
Australia

Mobile	s47F
Mail	s47F @klsmartin.com
Web	www.klsmartin.com

From: s 47E(d) @health.gov.au>

Sent: Tuesday, October 17, 2023 10:34 AM
To: s47F @klsmartin.com>
Subject: RE: Prescribed List - Condition on billing codes for surgical guides and biomodels [SEC=OFFICIAL]

Dear s47F

The condition applies to reimbursement of surgical guides and biomodels, not the devices with which they are used.

There are several items in the MBS for services involving insertion of craniomaxillofacial implants, so they were not named in the condition.

The condition reflects the criterion for listing that a device that is not surgically implanted should be integral to implanting a medical device on the PL. Private health insurers are not required to reimburse for surgical guides and biomodels that are used in services not involving an implant listed on the PL. This has not changed.

I hope this explains the situation for you.

Kind regards

Prostheses List Administration Section
Prostheses List Reforms Task Force
Technology Assessment and Access Division | Health Resourcing Group
Australian Government Department of Health and Aged Care
PO Box 9848, Canberra ACT 2601, Australia

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---

From: s 4 @klsmartin.com>
Sent: Monday, 16 October 2023 4:52 PM
To: s 47E(d) @health.gov.au>
Subject: RE: Prescribed List - Condition on billing codes for surgical guides and biomodels [SEC=OFFICIAL]

Hi
Sorry I should clarify that I'm referring to the MBS codes rather than rebate codes, apologies for the confusion.

Are there MBS code restrictions on any procedures within the Plastic and Reconstructive category or would all procedures with MBS codes within Plastic and Reconstructive still be eligible (excluding 07.05 and 07.06)?

Best Regards,

s47F
s 47F
Craniomaxillofacial Implants

KLS Martin Australia Pty Limited

23/2-6 Chaplin Drive
Lane Cove West NSW 2066
Australia

Mobile	s47F
Mail	s47F @klsmartin.com
Web	www.klsmartin.com

From: s47F
Sent: Monday, October 16, 2023 4:30 PM
To: s 47E(d) @health.gov.au>
Cc: s47F @klsmartin.com>; s47F @klsmartin.com>
Subject: RE: Prescribed List - Condition on billing codes for surgical guides and biomodels [SEC=OFFICIAL]

Hi,
Thanks for your reply. I understand the changes refer to surgical guides and biomodels, however my enquiry is around the product subgroups that currently utilise surgical guides and/or biomodels that are in different subcategories to 07.02.
Specifically:
07.01 – Craniomaxillofacial Reconstruction and Fixation
07.03 – Dental Implants
07.04 - Distractor Systems

Are these subcategories still eligible for surgical guide and biomodel reimbursement?

Are you able to provide guidance on the billing codes within Category 07 – Plastic and Reconstructive that will be eligible for reimbursement of surgical guides and biomodels?

As these are patient specific designed and manufactured products and we already have surgeries booked for Nov 1 onwards, waiting until the circular is published will mean that sponsors have to bear the cost of any devices no longer eligible for reimbursement.

If you can provide clarity on this matter so that we can communicate to affected surgeons and patients with urgency, that would be appreciated.

Best Regards,

s47F
s47F
Craniomaxillofacial Implants

KLS Martin Australia Pty Limited

23/2-6 Chaplin Drive
Lane Cove West NSW 2066
Australia

Mobile s47F
Mail s47F @klsmartin.com
Web www.klsmartin.com

From: s 47E(d) @health.gov.au>
Sent: Monday, October 16, 2023 2:50 PM
To: s47F @klsmartin.com>
Cc: s47F @klsmartin.com>; s47F @klsmartin.com>
Subject: RE: Prescribed List - Condition on billing codes for surgical guides and biomodels [SEC=OFFICIAL]

Dear s47F
Thank you for your email.

The changes refer to surgical guides and biomodels. The affected subgroups include:
07.02.02.04
07.02.05.07
07.02.06.06
07.02.07.05
07.02.09

When the November 2023 Prostheses List is published, the Department will also publish a

Private Health Insurance circular explaining the changes including the conditions on surgical guides and biomodels.

Kind regards

Prescribed List Administration Section
Prescribed List Task Force

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

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From: s47F @klsmartin.com>
Sent: Monday, 16 October 2023 2:00 PM
To: s 47E(d) @health.gov.au>
Cc: s47F @klsmartin.com>; s 47F
s47F @klsmartin.com>
Subject: Re: Prescribed List - Condition on billing codes for surgical guides and biomodels [SEC=OFFICIAL]

Hi,

Can you please clarify the condition on billing codes please? Are the eligible billing codes all those used under Product Category 07-Plastic and Reconstructive?

Best Regards,

s47F
s47F
Craniomaxillofacial Implants

KLS Martin Australia Pty Limited

23/2-6 Chaplin Drive
Lane Cove West NSW 2066
Australia

Mobile	s47F
Mail	s47F @klsmartin.com
Web	www.klsmartin.com

From: s 47E(d) @health.gov.au>
Sent: Wednesday, 11 October 2023 6:11 PM
Subject: [EXTERNAL] Prescribed List - Condition on billing codes for surgical guides and biomodels [SEC=OFFICIAL]

Dear Sponsor

This email is to inform you that following the Prescribed List (formerly known as Prostheses List) (PL) post-listing review, it has been decided to recommend placing a condition on the billing codes for surgical guides and biomodels listed on the PL. This will be reflected in the November 2023 PL.

The review report found that there is evidence to support the listing of these devices for the craniomaxillofacial procedures but not in any other procedures.

Medical Devices and Human Tissues Advisory Committee (MDHTAC) considered the above and agreed that the PL condition placed on the billing codes for these devices is warranted, specifying that Prescribed List reimbursement of the device is restricted to the use in craniomaxillofacial surgery procedures involving insertion of a medical device listed in Schedule 1.

MDHTAC also noted concerns about multiple devices being claimed per procedure when there is no apparent clinical need reflected in the claim documentation. MDHTAC recommended to the Minister's delegate that Prescribed List reimbursement of the device should be restricted to no more than 3 devices per procedure. Clinicians can use more than 3 devices per procedure, but the patient's insurer might need to be consulted on reimbursement for the additional devices.

The condition will be reflected in the draft PL that is expected to be available shortly.

Kind regards

Prostheses List Administration Section
Prostheses List Reforms Task Force
Technology Assessment and Access Division | Health Resourcing Group
Australian Government Department of Health and Aged Care
PO Box 9848, Canberra ACT 2601, Australia

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s22

From: s47E(d)
Sent: Thursday, 19 October 2023 4:23 PM
To: s 47F
Subject: New condition on billing codes for surgical guides and biomodels [SEC=OFFICIAL]

Dear stakeholder,

As discussed yesterday at the key stakeholder meeting, the new condition on billing codes for surgical guides and biomodels will be effective from 1 November 2023. More information is provided in the following PHI Circular: PHI 66/23 Private Health Insurance (Medical Devices and Human Tissue Products) Rules (No. 2) 2023 | Australian Government Department of Health and Aged Care

We ask that you please share this information with anyone that may be impacted by this change, particularly clinicians.

Regards,

Prostheses List Reform Taskforce

Technology Assessment and Access Division
Australian Government Department of Health and Aged Care
s47E(d) @health.gov.au

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We do not expect you to respond to this email outside your working hours. At the Department of Health and Aged Care we value and encourage flexible working. Feel free to read, act on or respond at a time that works for you.

s22

From: s 47F
Sent: Friday, 20 October 2023 2:41 PM
To: s47E(d)
Subject: PHI Circular 67/23

Hi,
I am writing to seek further clarification on the Circular released today to ensure Health Funds, Providers and Suppliers have clarity around how the rules will be applied.
May we request a list of all the Product sub-group and Billing Code this circular applies to?
The Act and PL Rules require that there is an associated MBS item number for the PL benefits to be payable by the Health Funds, could you provide a list of MBS items that are acceptable for the use of these bio-models and surgical guides.
There has been continued push back from health funds for paying on these devices. This will ensure there is no ambiguity around when the Health Funds need to pay and when the suppliers should be supplying these devices for.
Kind Regards

s47F
s 47F
Cabrini Health
Level 2, 141 Camberwell Road, HAWTHORN EAST VIC 3123 | www.cabrini.com.au
M: s47F | E: s 47F

---

s22

From: s47E(d)
Sent: Friday, 20 October 2023 2:22 PM
To: s47E(d)
Subject: Notification of PHI Circular 67/23 - New condition for surgical guides and biomodels listed on the Prescribed List [SEC=OFFICIAL]

Good afternoon

We would like to advise stakeholders that the following circular has been published on our website.

PHI 67/23 New condition for surgical guides and biomodels listed on the Prescribed List | Australian Government Department of Health and Aged Care

Regards,

Prostheses List Reform Taskforce

Technology Assessment and Access Division
Australian Government Department of Health and Aged Care
s47E(d) @health.gov.au

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From: s47F
To: s 47E(d)
Cc: s47F
Subject: RE: Prescribed List - Condition on billing codes for surgical guides and biomodels [SEC=OFFICIAL]
Date: Friday, 20 October 2023 3:43:30 PM
Attachments: image001.png
image003.png

Hi,

I just wanted to follow up on the below email in light of the advice in today's circular as it is generating significant confusion with clinical stakeholders. Regarding the previous advice that *"The condition applies to reimbursement of surgical guides and biomodels, not the devices with which they are used. There are several items in the MBS for services involving insertion of craniomaxillofacial implants, so they were not named in the condition."*, this appears to be inconsistent with the restrictions stated today that do, in fact, apply to the devices in which they are used.

"The PL reimbursement for surgical guides and biomodels is restricted to the procedures when these devices are used during the implantation/insertion of one of the implantable devices listed in any of the groups or sub-groups of the categories 07.01 - Craniomaxillofacial Reconstruction & Fixation or 07.02 - Craniomaxillofacial Implants. The PL reimbursement does not apply when surgical guides or biomodels are used for any procedures associated with implantation of a device not listed on the PL, or listed in other PL categories or sub-categories, or procedures that do not involve any implantation of a device or a product."

Based on this, no reimbursement of surgical guides and biomodels would be available for use in subcategory 07.04 – Distractor Systems. The products in this category are exclusively for craniomaxillofacial surgery, often cleft lip and palate patients and models and guides are essential as the bone quality in cleft patients is generally poor. Guided surgery is required to ensure device implantation into adequate bone. Hopefully this is an oversight, please clarify.

I also just want to clarify about dental implant guides, whether these are now ineligible? The associated implantable device sits under 07.03 – Dental Implants. We want to ensure we provide accurate information to clinical stakeholders.

Thank you.

Best Regards,

s47F
s47F
Craniomaxillofacial Implants

KLS Martin Australia Pty Limited

23/2-6 Chaplin Drive
Lane Cove West NSW 2066
Australia

Mobile s47F
Mail s47F @klsmartin.com

Web www.klsmartin.com

From: s 47E(d) @health.gov.au>
Sent: Tuesday, October 17, 2023 10:34 AM
To: s47F @klsmartin.com>
Subject: RE: Prescribed List - Condition on billing codes for surgical guides and biomodels [SEC=OFFICIAL]

Dear s47F

The condition applies to reimbursement of surgical guides and biomodels, not the devices with which they are used.

There are several items in the MBS for services involving insertion of craniomaxillofacial implants, so they were not named in the condition.

The condition reflects the criterion for listing that a device that is not surgically implanted should be integral to implanting a medical device on the PL. Private health insurers are not required to reimburse for surgical guides and biomodels that are used in services not involving an implant listed on the PL. This has not changed.

I hope this explains the situation for you.

Kind regards

Prostheses List Administration Section
Prostheses List Reforms Task Force
Technology Assessment and Access Division | Health Resourcing Group
Australian Government Department of Health and Aged Care
PO Box 9848, Canberra ACT 2601, Australia

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From: s47F @klsmartin.com>
Sent: Monday, 16 October 2023 4:52 PM
To: s 47E(d) @health.gov.au>
Subject: RE: Prescribed List - Condition on billing codes for surgical guides and biomodels [SEC=OFFICIAL]

Hi
Sorry I should clarify that I'm referring to the MBS codes rather than rebate codes, apologies for the confusion.

Are there MBS code restrictions on any procedures within the Plastic and Reconstructive category or would all procedures with MBS codes within Plastic and Reconstructive still be eligible (excluding 07.05 and 07.06)?

Best Regards,

s47F
s47F
Craniomaxillofacial Implants

KLS Martin Australia Pty Limited

23/2-6 Chaplin Drive
Lane Cove West NSW 2066
Australia

Mobile	s47F
Mail	s47F @klsmartin.com
Web	www.klsmartin.com

From: s47F
Sent: Monday, October 16, 2023 4:30 PM
To: s 47E(d) @health.gov.au>
Cc: s47F @klsmartin.com>; s47F @klsmartin.com>
Subject: RE: Prescribed List - Condition on billing codes for surgical guides and biomodels [SEC=OFFICIAL]

Hi,
Thanks for your reply. I understand the changes refer to surgical guides and biomodels, however my enquiry is around the product subgroups that currently utilise surgical guides and/or biomodels that are in different subcategories to 07.02.
Specifically:
07.01 – Craniomaxillofacial Reconstruction and Fixation
07.03 – Dental Implants
07.04 - Distractor Systems

Are these subcategories still eligible for surgical guide and biomodel reimbursement?

Are you able to provide guidance on the billing codes within Category 07 – Plastic and Reconstructive that will be eligible for reimbursement of surgical guides and biomodels?

As these are patient specific designed and manufactured products and we already have surgeries booked for Nov 1 onwards, waiting until the circular is published will mean that sponsors have to bear the cost of any devices no longer eligible for reimbursement.

If you can provide clarity on this matter so that we can communicate to affected surgeons and patients with urgency, that would be appreciated.

Best Regards,

s47F
s47F
Craniomaxillofacial Implants

KLS Martin Australia Pty Limited

23/2-6 Chaplin Drive
Lane Cove West NSW 2066
Australia

Mobile s47F
Mail s47F @klsmartin.com
Web www.klsmartin.com

From: s 47E(d) @health.gov.au>
Sent: Monday, October 16, 2023 2:50 PM
To: s47F @klsmartin.com>
Cc: s47F @klsmartin.com>; s47F @klsmartin.com>
Subject: RE: Prescribed List - Condition on billing codes for surgical guides and biomodels [SEC=OFFICIAL]

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Dear s47F
Thank you for your email.

The changes refer to surgical guides and biomodels. The affected subgroups include:
07.02.02.04
07.02.05.07
07.02.06.06
07.02.07.05
07.02.09

When the November 2023 Prostheses List is published, the Department will also publish a Private Health Insurance circular explaining the changes including the conditions on surgical guides and biomodels.

Kind regards

Prescribed List Administration Section
Prescribed List Task Force

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

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From: s47F @klsmartin.com>
Sent: Monday, 16 October 2023 2:00 PM
To: s 47E(d) @health.gov.au>
Cc: s47F @klsmartin.com>; s47F @klsmartin.com>
Subject: Re: Prescribed List - Condition on billing codes for surgical guides and biomodels [SEC=OFFICIAL]

Hi,

Can you please clarify the condition on billing codes please? Are the eligible billing codes all those used under Product Category 07-Plastic and Reconstructive?

Best Regards,

s47F
s47F
Craniomaxillofacial Implants

KLS martin GROUP

KLS Martin Australia Pty Limited

23/2-6 Chaplin Drive
Lane Cove West NSW 2066

Australia

Mobile s47F
Mail s47F @klsmartin.com
Web www.klsmartin.com

From: s 47E(d) @health.gov.au>
Sent: Wednesday, 11 October 2023 6:11 PM
Subject: [EXTERNAL] Prescribed List - Condition on billing codes for surgical guides and biomodels [SEC=OFFICIAL]

Dear Sponsor

This email is to inform you that following the Prescribed List (formerly known as Prostheses List) (PL) post-listing review, it has been decided to recommend placing a condition on the billing codes for surgical guides and biomodels listed on the PL. This will be reflected in the November 2023 PL.

The review report found that there is evidence to support the listing of these devices for the craniomaxillofacial procedures but not in any other procedures.

Medical Devices and Human Tissues Advisory Committee (MDHTAC) considered the above and agreed that the PL condition placed on the billing codes for these devices is warranted, specifying that Prescribed List reimbursement of the device is restricted to the use in craniomaxillofacial surgery procedures involving insertion of a medical device listed in Schedule 1.

MDHTAC also noted concerns about multiple devices being claimed per procedure when there is no apparent clinical need reflected in the claim documentation. MDHTAC recommended to the Minister's delegate that Prescribed List reimbursement of the device should be restricted to no more than 3 devices per procedure. Clinicians can use more than 3 devices per procedure, but the patient's insurer might need to be consulted on reimbursement for the additional devices.

The condition will be reflected in the draft PL that is expected to be available shortly.

Kind regards

Prostheses List Administration Section
Prostheses List Reforms Task Force
Technology Assessment and Access Division | Health Resourcing Group
Australian Government Department of Health and Aged Care
PO Box 9848, Canberra ACT 2601, Australia

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s22

From: s22
Sent: Friday, 20 October 2023 12:19 PM
To: s22 ; s22
Cc: s22
Subject: RE: Surgical Guides and Biomodels [SEC=OFFICIAL:Sensitive]

Hi s22

Thank you for this. I have transferred the text into the PHI circular template D23-3804325. I did a bit of restructuring and added some headings and bullet point in the hope that this will help with the flow and make it very clear for stakeholders.

Grateful if you can have a quick look and see if you are ok with what I've done. I will then get this to webteam.

s22

From: s22 @health.gov.au>
Sent: Friday, 20 October 2023 11:46 AM
To: s22 @Health.gov.au>; s22 @Health.gov.au>
Cc: s22 @health.gov.au>
Subject: RE: Surgical Guides and Biomodels [SEC=OFFICIAL:Sensitive]

Hi s22 and s22

My proposed text for the PHI Circular is below.

Condition on billing codes for surgical guides and biomodels

The Department has received a request for further clarification concerning the Private Health Insurance (Medical Devices and Human Tissue Products) Rules (No. 2) 2023, and specifically the condition placed on the Prescribed List billing codes for the surgical guides and biomodels listed on the PL in the Plastic and Reconstructive category, in subcategories of devices used in craniomaxillofacial (CMF) surgery (in subgroups 07.02.02.04, 07.02.05.07, 07.02.06.06, 07.02.07.05 and group 07.02.09).

The rationale and intent for the condition have already been included in the Explanatory Statement for the MDHTP Rules, but this PHI Circular provides further clarification.

By the condition, the PL reimbursement for surgical guides and biomodels is restricted to the procedures when these devices are used during the implantation/insertion of one of the implantable devices listed in any of the groups or sub-groups of the categories 07.01 - Craniomaxillofacial Reconstruction & Fixation or 07.02 - Craniomaxillofacial Implants. The PL reimbursement does not apply when surgical guides or biomodels are used for any procedures associated with implantation of a device not listed on the PL, or listed in other PL categories or sub-categories, or procedures that do not involve any implantation of a device or a product.

In respect to maximum number of 3 surgical guides or biomodels, the intent is that for any claims for the implantation procedures [defined by the respective MBS items stated in the claims] for a patient, insurers are not mandated to pay more than 3 PL benefits for any billing codes for surgical guides or biomodels, or no more than 6 benefits if both surgical guides and biomodels (maximum 3 for each) have been used in an implantation procedure for a patient. This restriction is not impacted by a number of devices implanted during a procedure.

Thank you

s 22

Director, Prostheses List Administration

Prostheses List Reform Taskforce
Location Sirius Building, s 22

s 22

From: s47E(d)
To: s47E(d)
Subject: Notification of PHI Circular 67/23 - New condition for surgical guides and biomodels listed on the Prescribed List [SEC=OFFICIAL]
Date: Friday, 20 October 2023 2:26:55 PM
Attachments: image001.png

Good afternoon

We would like to advise stakeholders that the following circular has been published on our website.

PHI 67/23 New condition for surgical guides and biomodels listed on the Prescribed List | Australian Government Department of Health and Aged Care

Regards,

Prostheses List Reform Taskforce
Technology Assessment and Access Division
Australian Government Department of Health and Aged Care
s47E(d) @health.gov.au

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We do not expect you to respond to this email outside your working hours. At the Department of Health and Aged Care we value and encourage flexible working. Feel free to read, act on or respond at a time that works for you.

From: s47E(d)
To: s47E(d) ; Prostheses/Health
Subject: Clarification on the new condition for surgical guides and biomodels listed on the Prescribed List [SEC=OFFICIAL]
Date: Friday, 20 October 2023 3:11:00 PM
Attachments: image001.png

Good afternoon

Following a few queries, we have issued a clarification on the new condition for surgical guides and biomodels, effective from 1 November 2023. We ask that you distribute this information to relevant stakeholders.

The PL reimbursement for surgical guides and biomodels is restricted to the procedures when these devices are used during the implantation/insertion of one of the implantable devices listed in any of the groups or sub-groups of the categories 07.01 - Craniomaxillofacial Reconstruction & Fixation or 07.02 - Craniomaxillofacial Implants. The PL reimbursement does not apply when surgical guides or biomodels are used for any procedures associated with implantation of a device not listed on the PL, or listed in other PL categories or sub-categories, or procedures that do not involve any implantation of a device or a product.

In respect to maximum number of 3 surgical guides or biomodels, the meaning is that for any claims for the implantation procedures (defined by the respective MBS items stated in the claims) for a patient, insurers are not mandated to pay more than 3 PL benefits for any billing codes for surgical guides or biomodels, or no more than 6 benefits if both surgical guides and biomodels (maximum 3 for each) have been used in an implantation procedure for a patient. This restriction is not impacted by a number of devices implanted during a procedure.

This information can also be found at: PHI 67/23 New condition for surgical guides and biomodels listed on the Prescribed List | Australian Government Department of Health and Aged Care

Regards,

Prostheses List Reform Taskforce
Technology Assessment and Access Division
Australian Government Department of Health and Aged Care
s47E(d) @health.gov.au

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s22

From: s47E(d)
Sent: Thursday, 19 October 2023 5:38 PM
To: s47E(d)
Subject: FOR INFORMATION: Key stakeholder meeting presentations and action items [SEC=OFFICIAL]
Attachments: Presentation Agenda item 3 - PL reforms update - Key stakeholder meeting 18 October 2023.pdf; Presentation Agenda item 2 - HPP update - Key stakeholder meeting 18 October 2023.pdf

Dear key stakeholder,

Thank you for attending yesterday's meeting on Prostheses List Reforms. Please find attached the slides that were presented at the meeting. There were 2 action items:

- Action item 1: The department to consider ways of sharing evaluation framework
- Action item 2 (completed): We have sent notification of PHI Circular 66 (which includes details on new condition for surgical guides and biomodels) to relevant stakeholders and ask for their support to disseminate the information.

Regards,

Prostheses List Reform Taskforce

Technology Assessment and Access Division
Australian Government Department of Health and Aged Care
s47E(d) @health.gov.au

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Key stakeholder meeting

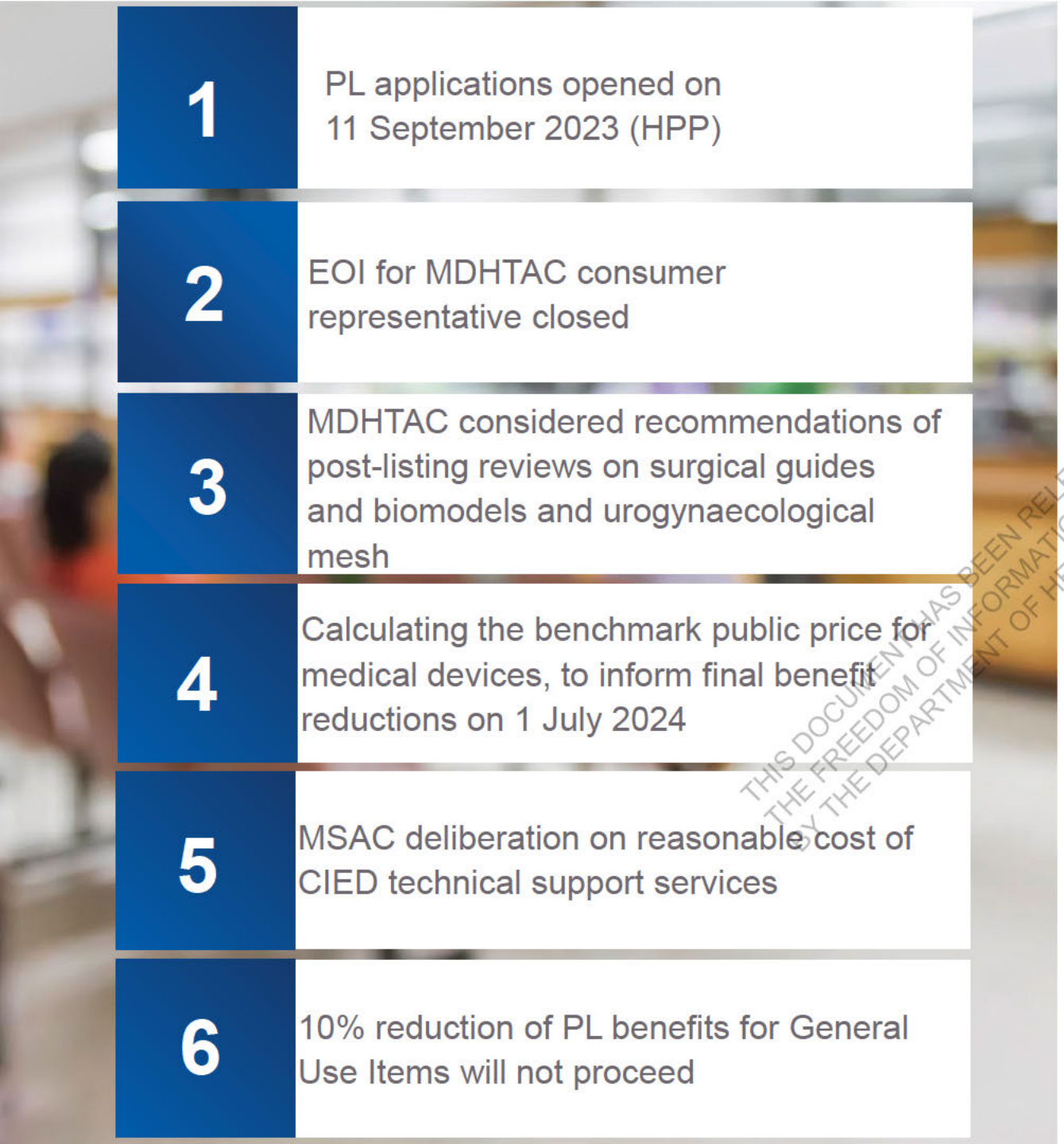
18 October 2023

Agenda Item 3 – Update on the PL Reforms

s22

Update

- Governance
- Prescribed List Guide
- Regrouping and mixed benefits
- Compliance and assurance
- Legislative amendments
- General Use Items
- Post-listing reviews
- Benchmarking
- Reforms evaluation
- CIEDs
- Consultation schedule September-November 2023



1. PL applications opened on 11 September 2023 (HPP)
2. EOI for MDHTAC consumer representative closed
3. MDHTAC considered recommendations of post-listing reviews on surgical guides and biomodels and urogynaecological mesh
4. Calculating the benchmark public price for medical devices, to inform final benefit reductions on 1 July 2024
5. MSAC deliberation on reasonable cost of CIED technical support services
6. 10% reduction of PL benefits for General Use Items will not proceed

Highlights of the reforms

August - October 2023

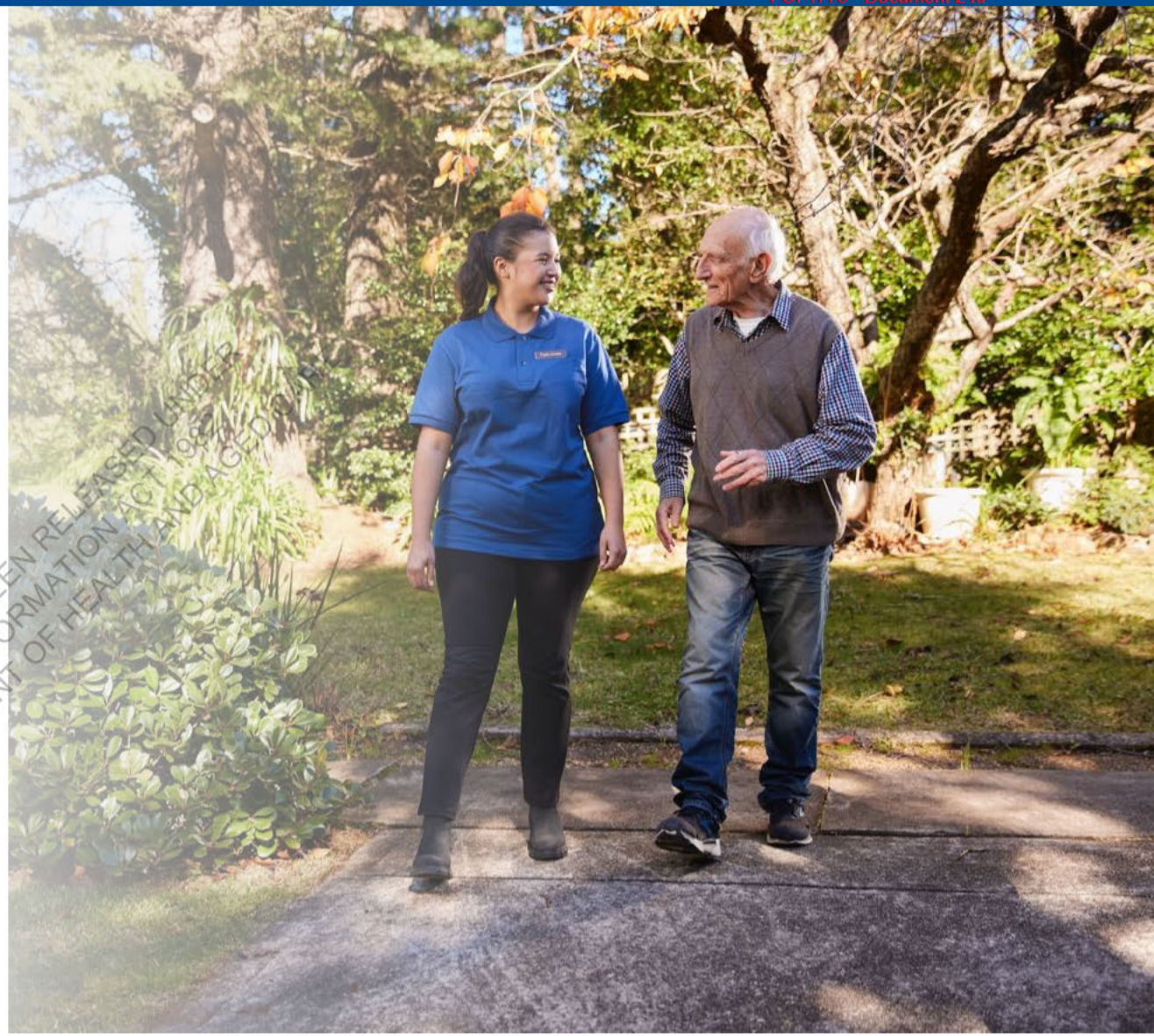
Governance

MDHTAC

- EOI for consumer representative closed on 15 September 2023
- The consumer representative will be appointed around November 2023
- Second MDHTAC meeting scheduled for mid-December 2023

Prescribed List Guide

- Currently finalising second version of the Guide
- A second targeted consultation is planned for late October 2023
- We are aiming to publish the second version of the Guide in early November 2023
- MTAA is facilitating a PL application training on 8 November 2023, with participation of the department and the MDHTAC Chair



Regrouping and mixed benefits

Part A

There are three main drivers of mixed benefits:

- Size
- System
- Suffixes

Suffixes

We continue working on the Special Orthopaedic Category

- Comparing data between devices with and without suffixes to inform the reviews
- We expect to have a proposed approach for ECAG's consideration in November, and MDHTAC in December

System

We have commenced work on options to address these groups that is consistent with how the PL benefits for cardiac ablation devices are capped in the legislation.

Regrouping and mixed benefits

Part B

- Consultation on PricewaterhouseCoopers (PWC) report concluded on 6 October 2023, with special focus on:
    - Report
    - Our response to PWC's recommendations
    - Proposed regrouping
- We received 20 submissions
- Working through feedback, which will inform next steps

Compliance and assurance

Consultation Paper 7 – Proposed measures for compliance, assurance and information sharing

Consultation Paper 7 closed on 10 August 2023.

We received 20 submissions. Some key topics raised were:

- Disparity of sanctions across stakeholders
- Data security
- Extra costs associated with record keeping obligations
- Potential detrimental effects of sanctions on patients

We will publish the stakeholder feedback report in the coming month.

Legislative amendments

Tranche 3: Legislative amendments to support compliance, assurance and information sharing activities

Ongoing internal discussions about proposed measures for inclusion in primary legislation (considering feedback to Consultation Paper 7)

Amendments are now expected to be introduced into Parliament during the 2024 Winter/Spring sitting periods.

We will be holding a webinar on 19 October 2023 (tomorrow) to walk through the set of measures that will be included in legislation.

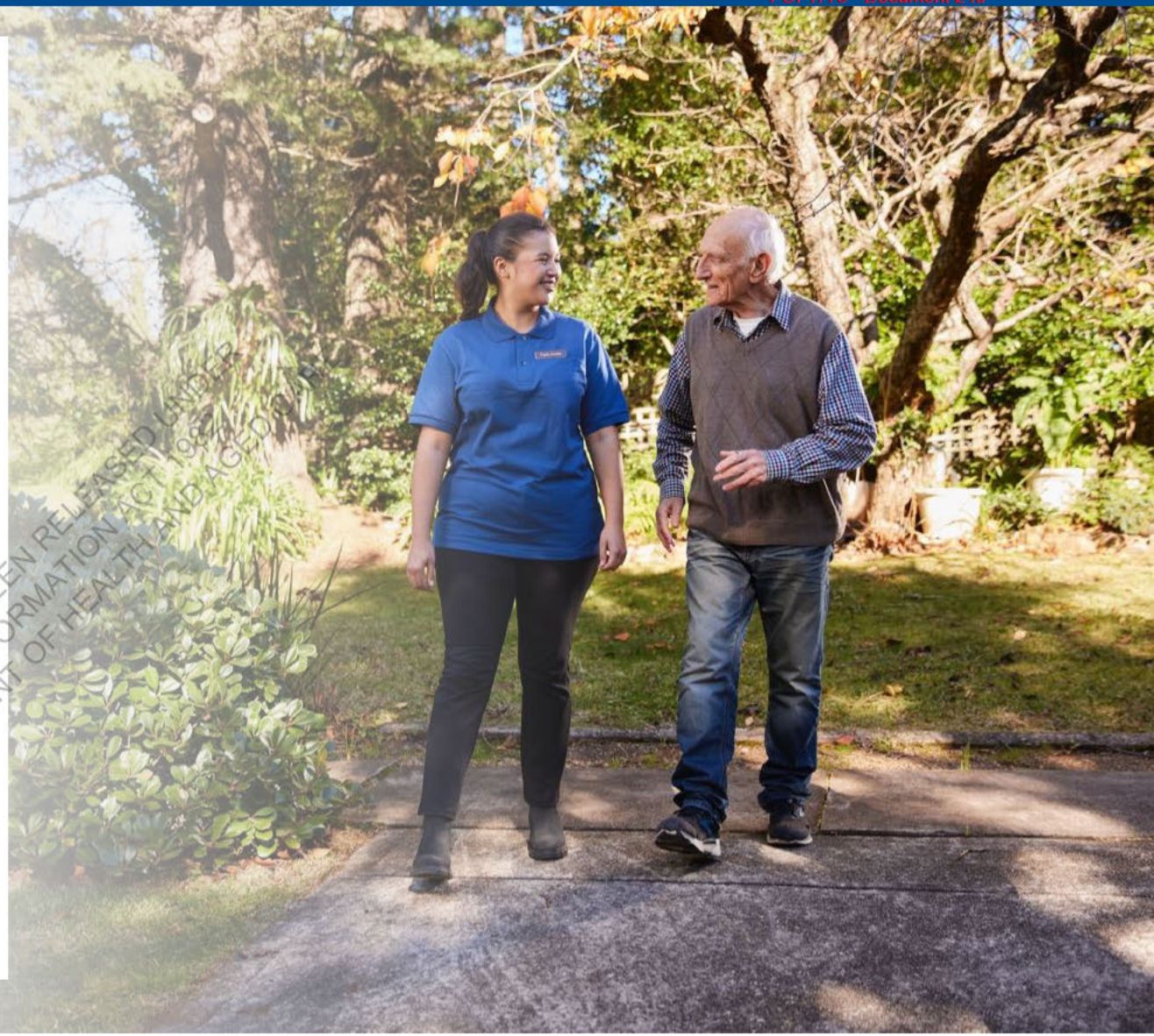
General Use Items (GUIs)

The further 10% reduction of PL benefits, which was to take effect on 1 November 2023, will no longer proceed.

Current Part D PL listings of GUIs will be retained until the items are removed from 1 July 2024.

Multi-stage discussions between insurer and hospital groups to establish an agreed alternative funding option for GUIs upon removal from PL

- The department will continue to convene meetings to support these discussions



Post-listing reviews

Surgical guides and biomodels

- The final report and recommendations were considered by MDHTAC in September 2023
- Outcome: Condition will be placed on billing codes – benefits will only apply to devices used in craniomaxillofacial and dental surgeries involving insertion of a medical device listed on the PL. A maximum of 3 devices can be claimed per procedure.
    - This condition will be applied to 53 billing codes in subgroups 07.02.02.04, 07.02.05.07, 07.02.06.06, 07.02.07.05 and group 07.02.09.
- Amendments to these listing will be incorporated in the 1 November 2023 PL update

Urogynaecological mesh (mid-urethral slings)

- The draft report and recommendations were considered by MDHTAC in September 2023
- Outcome: MDHTAC noted the advice to continue to list both Retropubic mid-urethral sling (RP-MUS) and Transobturator mid-urethral sling (TO-MUS) devices on the PL.

Post-listing reviews (continued)

Spinal cord stimulators

- Report and recommendations will be considered by the Spinal and Neurosurgical ECAG in November 2023, followed by MDHTAC in December 2023
- Where amendments to these listings are required, they will be incorporated in the 1 July 2024 PL update

Post-listing review framework

- Reminder that consultation remains open to key stakeholders
- The amended framework will be released for broad consultation in early 2024.

Calculating benchmark price

The third benefit reduction of 20% of the gap for Part A (non CIEDs) is scheduled for 1 July 2024.

As per the Memorandum of Understanding, IHACPA is required to recalculate weighted average price (WAP) for the 2022-23 FY, based on data from 1 July 2022 to 30 June 2023.

This recalculated WAP will inform the third 20% benefit reduction.

PL device level data for the 2022-23 FY for medical devices listed on the PL was requested from sponsors on 25 August 2023, with a due date of 31 October 2023 – a reminder will be sent out shortly.

- Any delays may lead to IHACPA relying on data collected for the 2021-22 FY

IHACPA will follow the same methodology as for the 2020/21 WAP.

Reforms evaluation

Nous has access to HCP1 data for evaluation purposes.

The next internal evaluation team meeting, and the stakeholder advisory group meeting scheduled for mid-November 2023.

Baseline evaluation report due from Nous on 30 November 2023.

CIEDs

- MSAC deliberation on reasonable cost for CIED technical services was finalised at the end of July 2023
- MSAC provided the Public Summary Document (PSD) to the applicant in August 2023
- An implementation plan for reductions to technical component of the PL benefit is currently under development
- Public communication and publication of the Public Summary Document (PSD) is imminent

Consultation schedule (September - November 2023)

HPP user onboarding webinars
Bi-weekly until November 2023

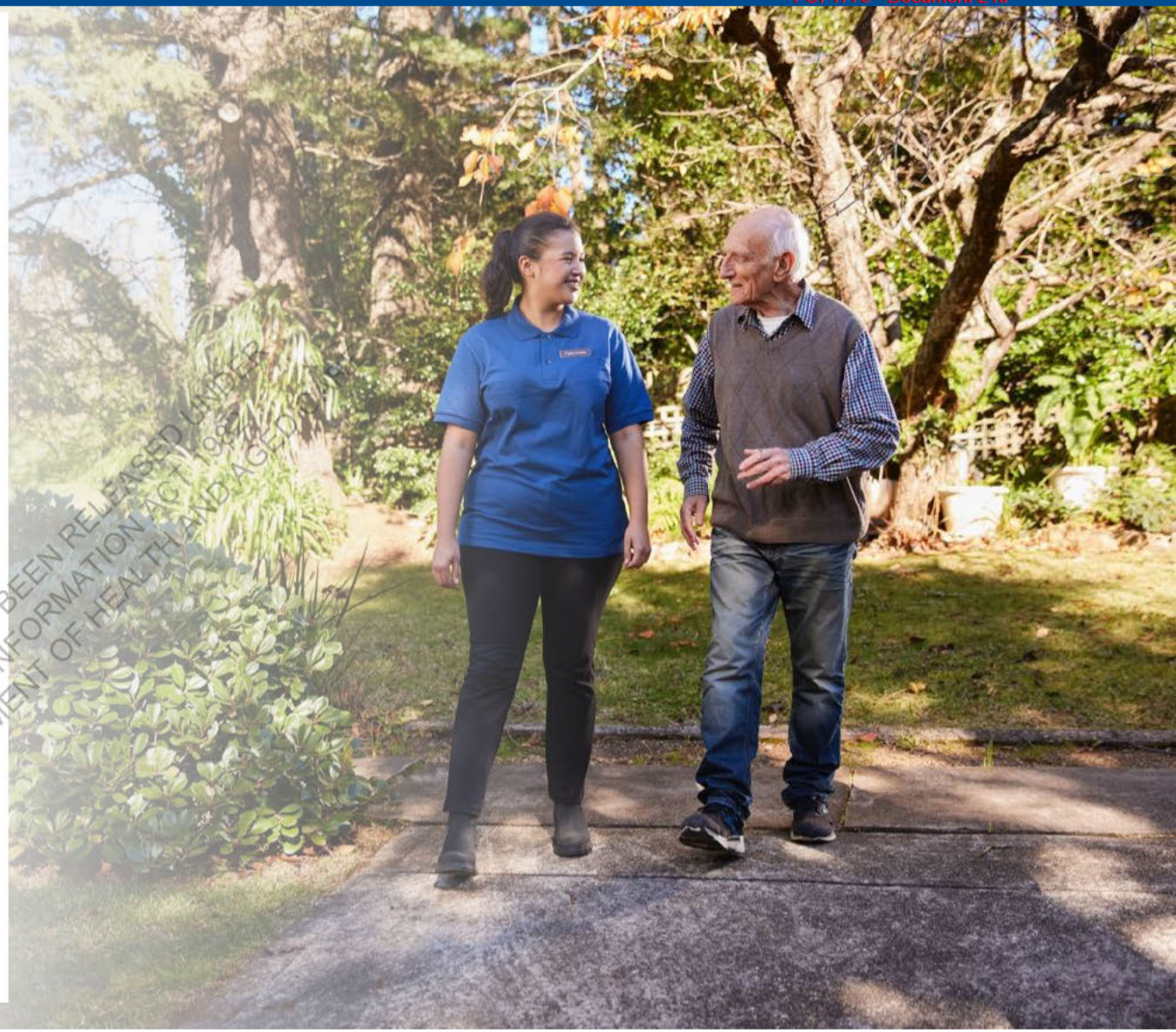
Part B reforms
6 week targeted consultation (closed on 6 October 2023)

Prescribed List Guide
Targeted consultation (expected late October/early November 2023)

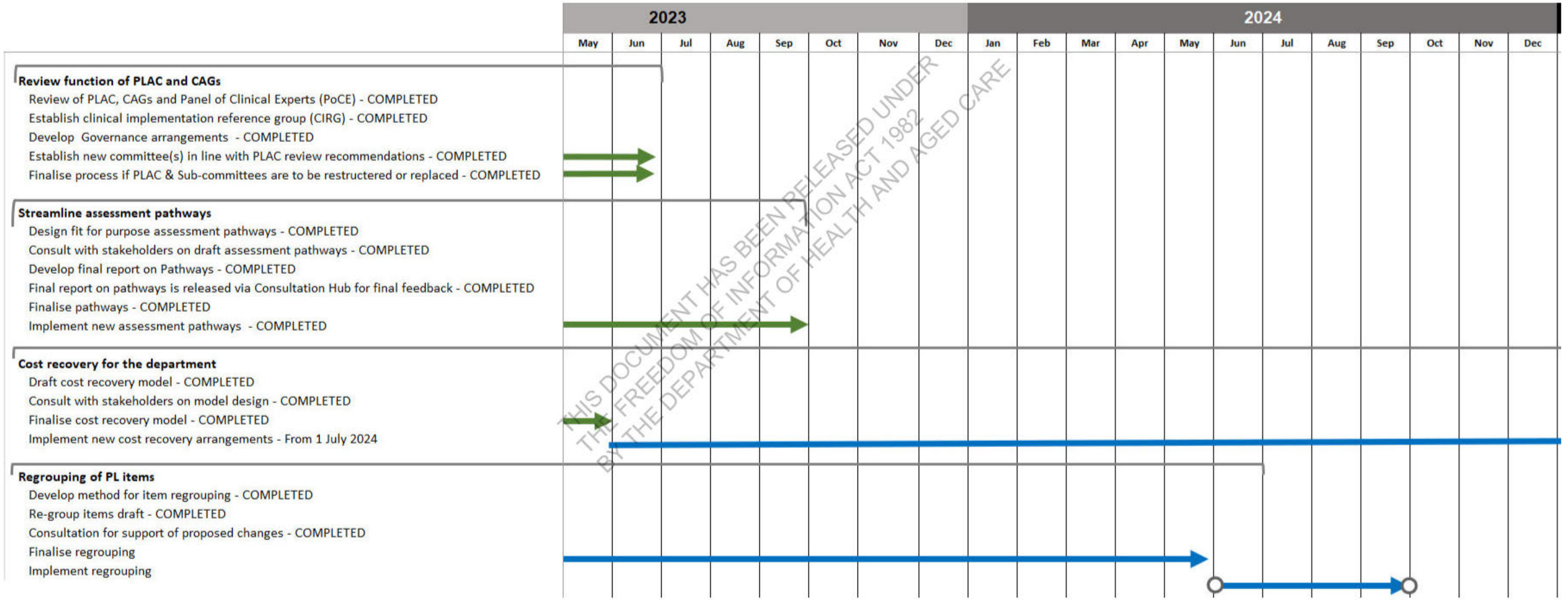
Webinar - Proposed measures for compliance, assurance and information sharing
Explanation of measures going into primary legislation (19 October 2023)

Timeline

As at October 2023



Administrative Arrangements October 2023



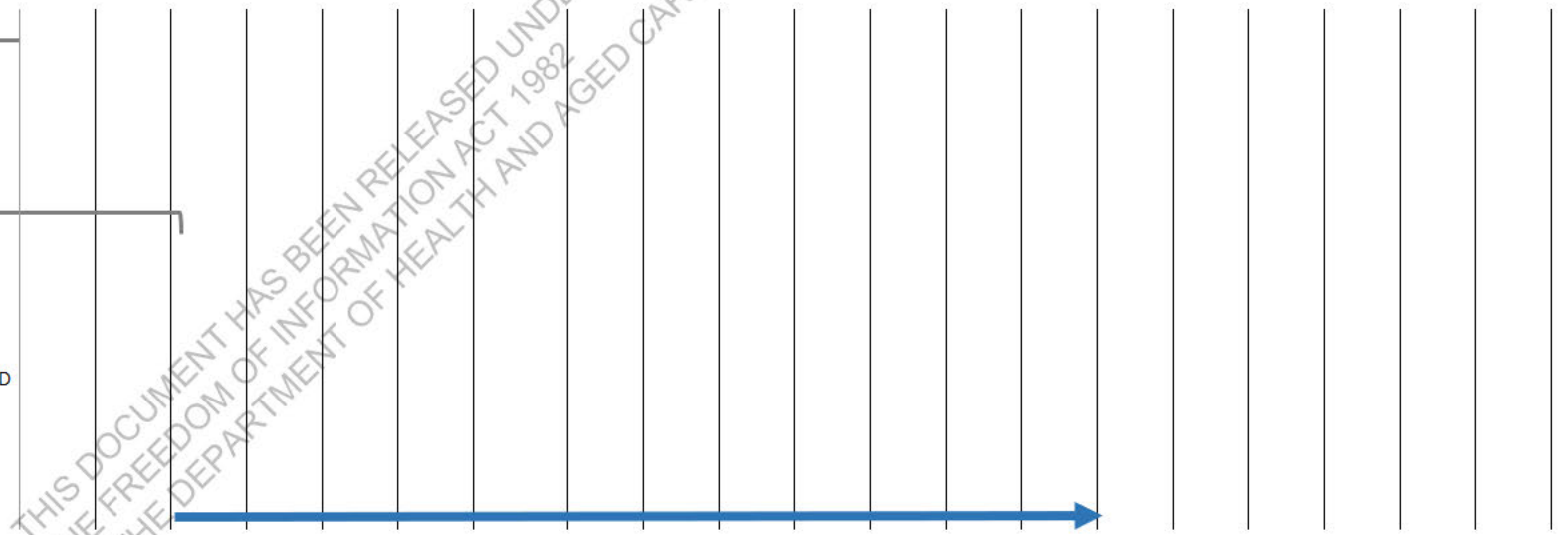
Structural Reforms October 2023

New definition of 'prostheses'

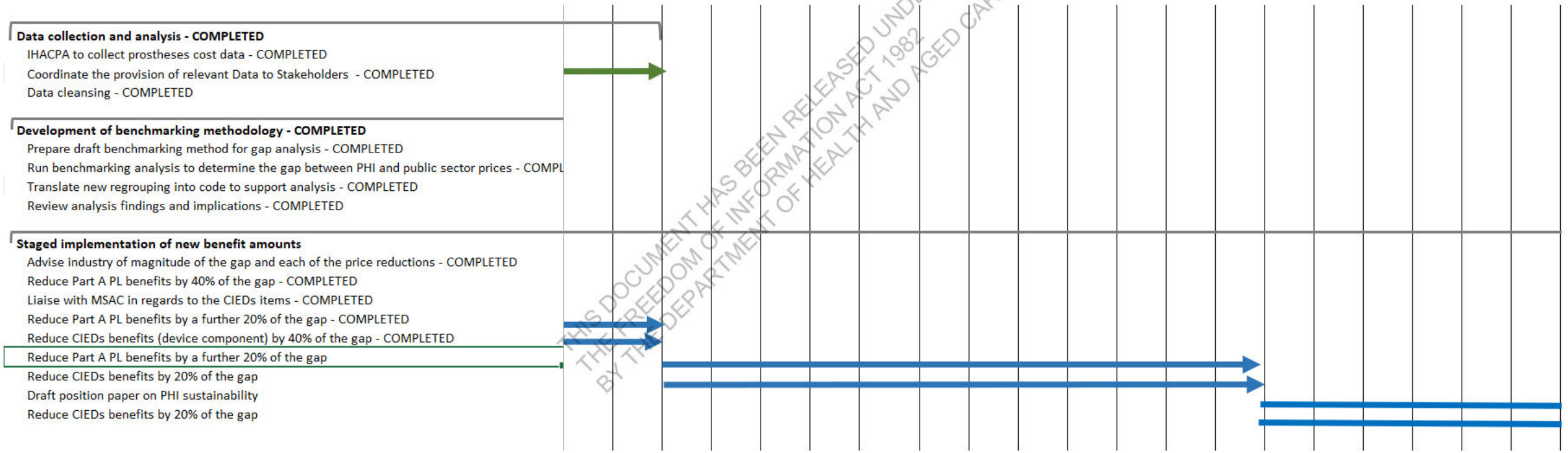
- Consultation paper - COMPLETED
- Consult internal stakeholders - COMPLETED
- Consult external stakeholders - COMPLETED
- Draft revised definition based on consultation process - COMPLETED

General Use items

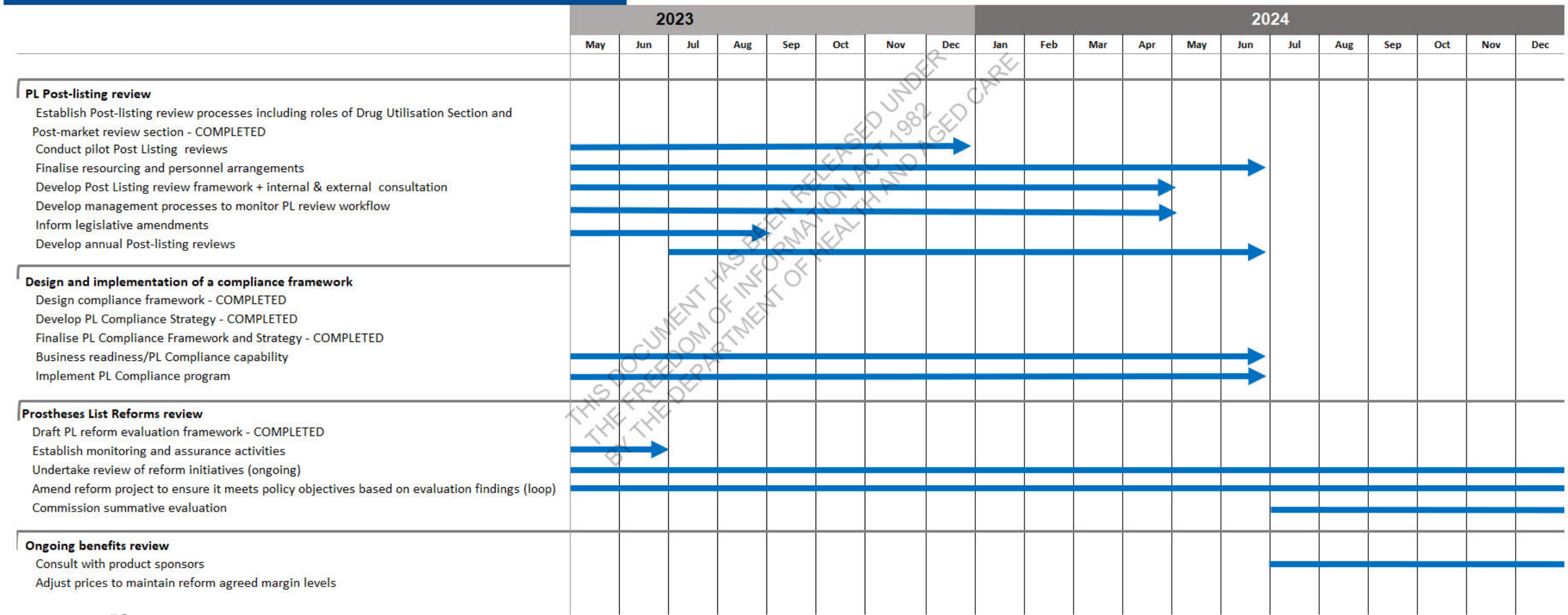
- Review items that do not fit with current PL definition - COMPLETED
- Review item list against revised PL scope to identify items no longer eligible - COMPLETED
- Engage with sponsors and PHI providers on proposed changes - COMPLETED
- Finalise reference pricing of general use items to public hospital prices - COMPLETED
- Engage with relevant sponsors on the identified gap and the two gap reductions - COMPLETED
- Reduce GU Items gap by 60% - COMPLETED
- Reduce GU Items gap by final 40% - COMPLETED
- Bundling advice from IHACPA for ineligible general use items - COMPLETED
- Remove GU items from the PL



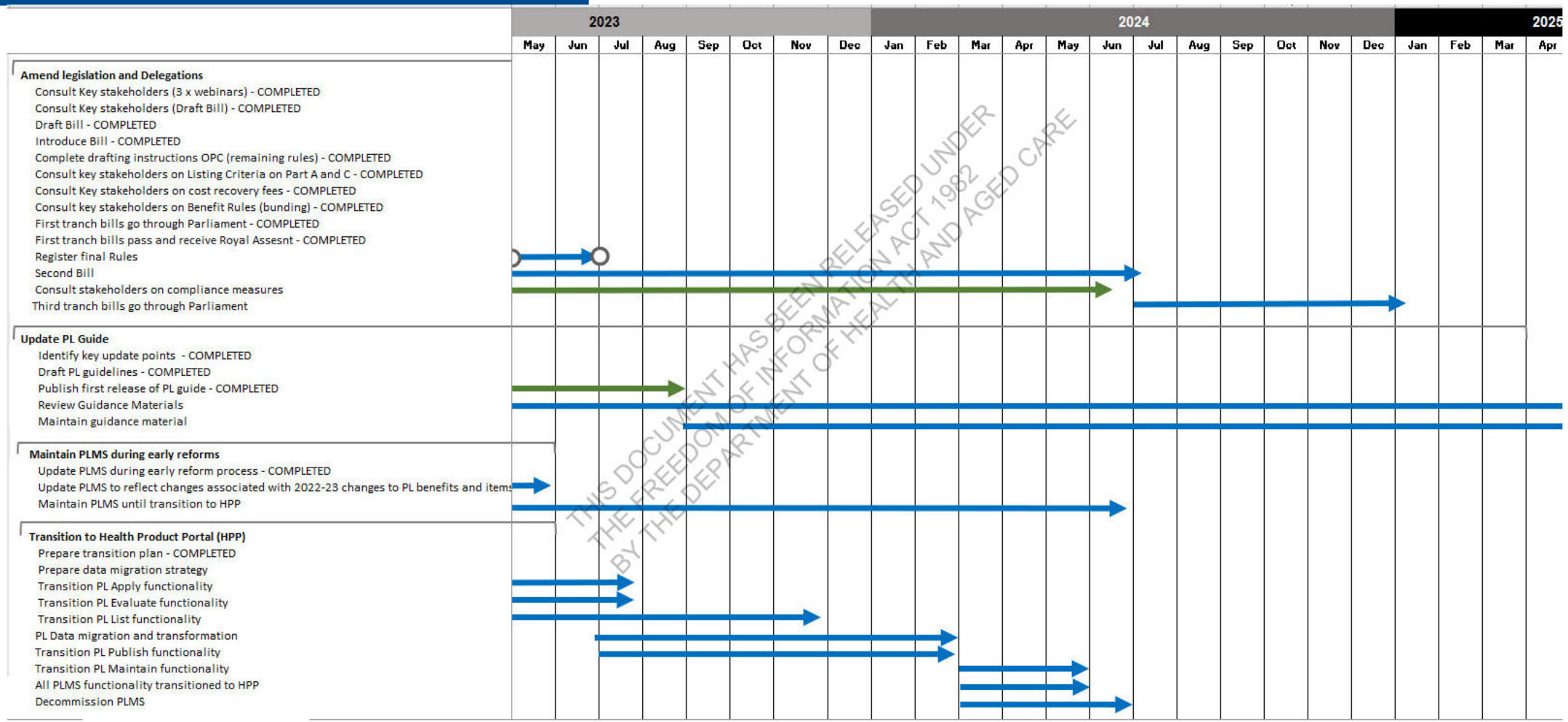
Reducing the gap
October 2023



Safeguarding the PL October 2023



Supporting activities October 2023



Getting in touch with us

Prostheses List

Applications

s47E(d) [redacted] @health.gov.au

Reforms

s47E(d) [redacted] @health.gov.au

Post-listing reviews

s47E(d) [redacted] @health.gov.au

Compliance

s22 [redacted] @health.gov.au

Health Products Portal (HPP)

s 47E(d) [redacted] @health.gov.au

Australian Government

Department of Health and Aged Care

From: s47F
To: s 47E(d)
Cc: s47F
Subject: RE: Quick clarification - FW: Prescribed List - Condition on billing codes for surgical guides and biomodels [SEC=OFFICIAL]
Date: Thursday, 19 October 2023 8:33:15 AM
Attachments: image002.png

Dear Prostheses List Administration Section,

Thank you for your response it is very helpful.

s47G(1)(a)

Thank you for your time

Kind regards,
s 47F

PHARMALEX

PharmaLex Pty Ltd (Sydney)
Level 10, 1 Chandos Street
St Leonards, NSW 2065, Australia
Phone: s47F
Mobile: s47F
Email: s 47F
www.pharmalex.com

From: s 47E(d) @health.gov.au>
Sent: Tuesday, October 17, 2023 4:39 PM
To: s47F
Cc: s47F
Subject: RE: Quick clarification - FW: Prescribed List - Condition on billing codes for surgical guides and biomodels [SEC=OFFICIAL]

Dear s47F

The Prescribed List sets out the medical devices and human tissue products that insurers must pay benefits for. Private health insurers can pay benefits for medical devices outside the PL arrangements, but this is at their discretion. So if a clinician uses more than 3 devices in the procedure, reimbursement would be a matter for the hospital and the patient.

Kind regards

Prostheses List Administration Section
Prostheses List Reforms Task Force
Technology Assessment and Access Division | Health Resourcing Group
Australian Government Department of Health and Aged Care
PO Box 9848, Canberra ACT 2601, Australia

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From: s 47F >
Sent: Tuesday, 17 October 2023 3:46 PM
To: s 47E(d) @health.gov.au>
Cc: s 47F >
Subject: Quick clarification - FW: Prescribed List - Condition on billing codes for surgical guides and biomodels [SEC=OFFICIAL]

Dear Prostheses List Administration Section,

We received the below, which has the following communication:
"Clinicians can use more than 3 devices per procedure, but the patient's insurer *might* need to be consulted on reimbursement for the additional devices."

However in the draft November list, it states:
"Prescribed List reimbursement of the device is restricted to the use in craniomaxillofacial surgery procedures involving insertion of a medical device listed in Schedule 1, and for no more than 3 devices per procedure."

s47G(1)(a)

Thank you for taking the time to provide clarification.

Please let me know if you require further information.

Kind regards,
s 47F

PHARMALEX
PharmaLex Pty Ltd (Sydney)
Level 10, 1 Chandos Street
St Leonards, NSW 2065, Australia
Phone: s47F
Mobile: s47F
Email: s 47F
www.pharmalex.com

From: s 47E(d) @health.gov.au>
Sent: Wednesday, 11 October 2023 6:11 PM
Subject: Prescribed List - Condition on billing codes for surgical guides and biomodels [SEC=OFFICIAL]

Dear Sponsor

This email is to inform you that following the Prescribed List (formerly known as Prostheses List) (PL) post-listing review, it has been decided to recommend placing a condition on the billing codes for surgical guides and biomodels listed on the PL. This will be reflected in the November 2023 PL.

The review report found that there is evidence to support the listing of these devices for the craniomaxillofacial procedures but not in any other procedures.

Medical Devices and Human Tissues Advisory Committee (MDHTAC) considered the above and agreed that the PL condition placed on the billing codes for these devices is warranted, specifying that Prescribed List reimbursement of the device is restricted to the use in craniomaxillofacial surgery procedures involving insertion of a medical device listed in Schedule 1.

MDHTAC also noted concerns about multiple devices being claimed per procedure when there is no apparent clinical need reflected in the claim documentation. MDHTAC recommended to the Minister's delegate that Prescribed List reimbursement of the device should be restricted to no more than 3 devices per procedure. Clinicians can use more than 3 devices per procedure, but the patient's insurer might need to be consulted on reimbursement for the additional devices.

The condition will be reflected in the draft PL that is expected to be available shortly.

Kind regards

Prostheses List Administration Section
Prostheses List Reforms Task Force
Technology Assessment and Access Division | Health Resourcing Group
Australian Government Department of Health and Aged Care
PO Box 9848, Canberra ACT 2601, Australia

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s22

From: s47E(d)
Sent: Thursday, 19 October 2023 4:23 PM
To: s 47F
Subject: New condition on billing codes for surgical guides and biomodels [SEC=OFFICIAL]

Dear stakeholder,

As discussed yesterday at the key stakeholder meeting, the new condition on billing codes for surgical guides and biomodels will be effective from 1 November 2023. More information is provided in the following PHI Circular: PHI 66/23 Private Health Insurance (Medical Devices and Human Tissue Products) Rules (No. 2) 2023 | Australian Government Department of Health and Aged Care

We ask that you please share this information with anyone that may be impacted by this change, particularly clinicians.

Regards,

Prostheses List Reform Taskforce

Technology Assessment and Access Division
Australian Government Department of Health and Aged Care
s47E(d) @health.gov.au

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From: s47F
To: s 47E(d)
Cc: s47F
Subject: Re: Prescribed List - Condition on billing codes for surgical guides and biomodels [SEC=OFFICIAL]
Date: Wednesday, 18 October 2023 1:06:48 PM
Attachments: image003.png
image004.png
image005.png

Hi Team

Thanks again for your response.
Could you please provide a definition of craniomaxillofacial surgery procedures in order to avoid ambiguity with the health funds?
Regards

s47F
Specifica Pty Ltd
p: s47F
a: C301, 16 Wurrook CCT
Caringbah NSW 2229

From: s 47E(d) @health.gov.au>
Sent: Tuesday, October 17, 2023 1:24 PM
To: s 47F
Cc: s 47F >
Subject: RE: Prescribed List - Condition on billing codes for surgical guides and biomodels [SEC=OFFICIAL]

Hi s47F

The wording of the condition is “Prescribed List reimbursement of the device is restricted to the use in craniomaxillofacial surgery procedures involving insertion of a medical device listed in Schedule 1, and for no more than 3 devices per procedure.”.

The condition will be communicated to stakeholders in a Private Health Insurance circular published on the Department’s website when the PL documents are published.

Kind regards

Prostheses List Administration Section
Prostheses List Reforms Task Force
Technology Assessment and Access Division | Health Resourcing Group
Australian Government Department of Health and Aged Care
PO Box 9848, Canberra ACT 2601, Australia

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From: s 47F >
Sent: Tuesday, 17 October 2023 12:18 PM
To: s 47E(d) @health.gov.au>
Cc: s 47F >
Subject: Re: Prescribed List - Condition on billing codes for surgical guides and biomodels [SEC=OFFICIAL]

Hi

Thank you for your further assistance.
Is it possible to have the wording of the condition which will be published in the circular? This will help us preparing our stake holders.

Moreover, will a document be issued explaining the reason for imposing the conditions following the post-listing review?

Thanks again.
Regards

s47F
Specifica Pty Ltd
p: +s47F
a: C301, 16 Wurrook CCT
Caringbah NSW 2229

From: s 47E(d) @health.gov.au>
Sent: Thursday, October 12, 2023 3:47 PM
To: s 47F Prostheses/Health s47E(d) @health.gov.au>
Cc: s 47F >
Subject: RE: Prescribed List - Condition on billing codes for surgical guides and biomodels [SEC=OFFICIAL]

Hi s47F

When the November 2023 Prostheses List is published, the Department will also publish a Private Health Insurance circular explaining the changes including the conditions on surgical guides and biomodels.

In the meantime, you have the email that alerts medical device sponsors about the condition.

Kind regards

Prostheses List Administration Section
Prostheses List Reforms Task Force
Technology Assessment and Access Division | Health Resourcing Group
Australian Government Department of Health and Aged Care
PO Box 9848, Canberra ACT 2601, Australia

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---

From: s 47F
Sent: Thursday, 12 October 2023 3:17 PM
To: s 47E(d) @health.gov.au>
Cc: s 47F
Subject: Re: Prescribed List - Condition on billing codes for surgical guides and biomodels [SEC=OFFICIAL]

Hi

Thank you for your prompt response.

s 47G

Thanks again
Regards

s47F
Specifica Pty Ltd
p: s47F
a: C301, 16 Wurrook CCT
Caringbah NSW 2229

From: s 47E(d) @health.gov.au>
Sent: Thursday, October 12, 2023 3:03 PM
To: s 47F
Subject: RE: Prescribed List - Condition on billing codes for surgical guides and biomodels [SEC=OFFICIAL]

Hi s47F

The condition will be applied from 1 November 2023.

The condition applies to each billing code, so 3 surgical guides and 3 biomodels.

Kind regards

Prostheses List Administration Section
Prostheses List Reforms Task Force
Technology Assessment and Access Division | Health Resourcing Group
Australian Government Department of Health and Aged Care
PO Box 9848, Canberra ACT 2601, Australia

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From: s 47F
Sent: Thursday, 12 October 2023 2:39 PM
To: s 47E(d) @health.gov.au>
Subject: Re: Prescribed List - Condition on billing codes for surgical guides and biomodels [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

Can you confirm the following two points:

- the start date the devices cannot be used in surgical procedures other than craniofacial surgery procedures is November 1st ?
- Is the devices limit as 3 biomodels and 3 surgical guides per procedure or 3 devices in total between models and guides?

Thank you
Regards

s47F
Specifica Pty Ltd
p: s47F
a: C301, 16 Wurrook CCT

Caringbah NSW 2229

From: s 47E(d) @health.gov.au>
Sent: Wednesday, October 11, 2023 6:10 PM
Subject: Prescribed List - Condition on billing codes for surgical guides and biomodels [SEC=OFFICIAL]

Dear Sponsor

This email is to inform you that following the Prescribed List (formerly known as Prostheses List) (PL) post-listing review, it has been decided to recommend placing a condition on the billing codes for surgical guides and biomodels listed on the PL. This will be reflected in the November 2023 PL.

The review report found that there is evidence to support the listing of these devices for the craniomaxillofacial procedures but not in any other procedures.

Medical Devices and Human Tissues Advisory Committee (MDHTAC) considered the above and agreed that the PL condition placed on the billing codes for these devices is warranted, specifying that Prescribed List reimbursement of the device is restricted to the use in craniomaxillofacial surgery procedures involving insertion of a medical device listed in Schedule 1.

MDHTAC also noted concerns about multiple devices being claimed per procedure when there is no apparent clinical need reflected in the claim documentation. MDHTAC recommended to the Minister's delegate that Prescribed List reimbursement of the device should be restricted to no more than 3 devices per procedure. Clinicians can use more than 3 devices per procedure, but the patient's insurer might need to be consulted on reimbursement for the additional devices.

The condition will be reflected in the draft PL that is expected to be available shortly.

Kind regards

Prostheses List Administration Section
Prostheses List Reforms Task Force
Technology Assessment and Access Division | Health Resourcing Group
Australian Government Department of Health and Aged Care
PO Box 9848, Canberra ACT 2601, Australia

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From: s 47E(d)
Bcc: s47F

s47F

Subject: PHI Circular 66/23 - Private Health Insurance (Medical Devices and Human Tissue Products) Rules (No. 2) 2023 [SEC=OFFICIAL]
Date: Wednesday, 18 October 2023 6:32:33 PM
Attachments: image003.png

Good afternoon

This email is to advise that PHI Circular 66/23 - Private Health Insurance (Medical Devices and Human Tissue Products) Rules (No. 2) 2023 has been published and is available on the Department of Health and Aged Care website at this link.

Kind regards

Prostheses List Administration Section
Prostheses List Reforms Task Force

Technology Assessment and Access Division | Health Resourcing Group
Australian Government Department of Health and Aged Care
PO Box 9848, Canberra ACT 2601, Australia

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From: s22
To: s22
Subject: FW: Prescribed List - Condition on billing codes for surgical guides and biomodels [SEC=OFFICIAL]
Date: Tuesday, 17 October 2023 9:33:06 AM
Attachments: image001.png
image004.png

Hi s22

Email from JJM received in Prostheses email box.

Regards

s22

s22
Assistant Director – Prostheses List Administration Section
Prostheses List Reforms Task Force
Technology Assessment and Access Division | Health Resourcing Group
Australian Government Department of Health and Aged Care
T: s22 | E s22 @health.gov.au
Location: s22 Sirius
PO Box 9848, Canberra ACT 2601, Australia

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From: s 47F @its.jnj.com>
Sent: Monday, 16 October 2023 3:57 PM
To: s 47E(d) @health.gov.au>; s47E(d) @Health.gov.au>
Cc: s 47F @ITS.JNJ.com>
Subject: RE: Prescribed List - Condition on billing codes for surgical guides and biomodels [SEC=OFFICIAL]

Dear Prescribed List Administration Section and Prescribed List Post-Listing Review Team,

Johnson and Johnson MedTech are very concerned about the lack of notice provided to patients, hospitals, clinicians and sponsors for the implementation of the new conditions on Guides and Biomodels. In particular, that reimbursement will be restricted to no more than 3 devices per procedure.

Providing less than three weeks' notice is inadequate for procedures that require up to three months planning and production.

Many patients who already have their procedures scheduled and devices manufactured have

done so without knowledge that they may in fact not have coverage for the devices being used. We provide (in confidence) a summary of the number of patients who will be impacted based on knowledge of our supply requirements for the next 90 days. Across all sponsors this number will be far greater.

Procedures scheduled in next 90 days

Total Cases	s47G(1)(a)
s47G(1)(a)	

To the best of our knowledge there has not been a circular to inform hospitals and clinicians of the new conditions. Surgeons are currently mid-way through planning more than 100 patient treatments without knowledge of this change. These patients have had scans and committed to surgical treatment.

We request urgent reconsideration of the timelines for implementation of the restriction to reimburse no more than 3 devices per procedure. Clinicians and hospitals need to be afforded the opportunity to plan and have an informed, timely, discussion with patients and their funds. This can only be done if implementation is delayed to 2024.

The patients who are impacted are those with the most complex requirements, i.e. where multiple craniomaxillofacial areas require surgery. Further, this time of year is when the greatest volume of patients have orthognathic surgery as it aligns with when patients and their carers have access to leave. We urgently request all stakeholders are given sufficient notice to understand and plan for these changes so they can make informed decisions. That cannot be done with a November 1, 2023 implementation.

s47F

s47F
Director, Health Economics Market Access
Australia & New Zealand

Johnson & Johnson
MedTech

Johnson & Johnson Medical Pty Ltd
P.O. Box 134, North Ryde, NSW 1670 Australia
T: s47F
M: s47F
s47F @its.jnj.com
http://www.jnj.com

From: s 47E(d) @health.gov.au>
Sent: Wednesday, 11 October 2023 6:11 PM
Subject: [EXTERNAL] Prescribed List - Condition on billing codes for surgical guides and biomodels [SEC=OFFICIAL]

Dear Sponsor

This email is to inform you that following the Prescribed List (formerly known as Prostheses List) (PL) post-listing review, it has been decided to recommend placing a condition on the billing codes for surgical guides and biomodels listed on the PL. This will be reflected in the November 2023 PL.

The review report found that there is evidence to support the listing of these devices for the craniomaxillofacial procedures but not in any other procedures.

Medical Devices and Human Tissues Advisory Committee (MDHTAC) considered the above and agreed that the PL condition placed on the billing codes for these devices is warranted, specifying that Prescribed List reimbursement of the device is restricted to the use in craniomaxillofacial surgery procedures involving insertion of a medical device listed in Schedule 1.

MDHTAC also noted concerns about multiple devices being claimed per procedure when there is no apparent clinical need reflected in the claim documentation. MDHTAC recommended to the Minister's delegate that Prescribed List reimbursement of the device should be restricted to no more than 3 devices per procedure. Clinicians can use more than 3 devices per procedure, but the patient's insurer might need to be consulted on reimbursement for the additional devices.

The condition will be reflected in the draft PL that is expected to be available shortly.

Kind regards

Prostheses List Administration Section
Prostheses List Reforms Task Force
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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