s22

From: s47F
Sent: Thursday, 26 October 2023 11:23 AM
To: PLATONA, Adriana
Cc: RINTOUL, Andrew; s22
Subject: FW: Condition on billing codes for surgical guides and biomodels [SEC=OFFICIAL]

Hi Adriana,

We have concerns about the implementation timeframes on the changes for surgical guides and biomodels that were announced on 18 October, with further clarification issued on 20 October. There still appears to be a lack of clarity around the impact of the changes and how they will be implemented. We also understand that a number of surgeries will now be cancelled. To ensure a smooth implementation and minimal impact on patients, we ask that this change is delayed while further detail and clear communications about the change is worked through with hospitals.

Happy to discuss further.

s47F

From: s22 @Health.gov.au>
Sent: Tuesday, 24 October 2023 12:16 PM
To: s47F @Health.gov.au>
Cc: RINTOUL, Andrew <Andrew.Rintoul@health.gov.au>; PLATONA, Adriana <Adriana.Platona@health.gov.au>; s22 @health.gov.au>
Subject: RE: Condition on billing codes for surgical guides and biomodels [SEC=OFFICIAL]

Dear s47F

Some background and detail about the new condition for surgical guides and biomodels that was announced on 18 October 2023 and effective 1 November 2023 for your information.

- The outcome of the post-listing review into surgical guides and biomodels was presented to the MDHTAC for consideration and advice at the September 2023 meeting. The key points considered were:
    - The post-listing review of surgical guides and biomodels was triggered by many concerns raised by stakeholders (including private health insurers, some sponsors and clinicians) regarding the questions about whether these devices meet the PL Part A criteria for listing.
    - The review report (that was undertaken by an external reviewer) concluded that surgical guides and biomodels have an established role in clinical practice predominantly in craniomaxillofacial (CMF) and oral surgery, and achieve comparable or improved outcomes by improving accuracy of implant placement, decreased operative and/or ischaemic time, reduced intraoperative fluoroscopy and reduced complication rates.
    - The review further advised that surgical guides and biomodels are considered eligible for listing on PL Part A, but their eligibility depends on the clinical circumstances in which they are used.
    - The department undertook additional targeted consultation with some clinical societies after the review report was received – specifically in the orthopaedic and spinal categories.
    - Formulating conditions that could be imposed to restrict PL reimbursement for billing codes under certain clinical scenarios is difficult.
- The MDHTAC members discussed the findings of the review and the types of clinical categories that are relevant for reimbursement of these devices. The key points were:

  - The MDHTAC advice to the delegate was that for these devices that are already listed on the PL and used in CMF and oral surgery to remain on the PL. There was no evidence to support listing of these devices on the PL in any other category at this point
  - The listings for these devices needs to be restricted to reimbursement when the device is used for CMF procedures, the implants for which the surgical guides or biomodels listed under the billing code may be used for the purposes of PL reimbursement need to be specified
  - Additional conditions may also include capping the number of devices that may be claimed per procedure or the total amount of benefits payable.
  - Finally, for any other type of surgery (eg. Orthopaedic), sponsors will be required to apply for listing of the device in that specific category and provide the satisfactory data to demonstrate that the devices are both essential for implantation of an implantable device and lead to improved clinical outcomes.
  - If clinicians determine additional numbers of devices are required in a single procedure, the hospital and insurer are able to negotiate reimbursement for the additional devices.
- The PHI Circular 66/23 released on 18 October 2023 provided information about the Private Health Insurance (Medical Devices and Human Tissue Products) Rules (No.2) 2023 that will be effective 1 November 2023 and included:
  - A range of changes to be applied to the PL based on the outcome of applications and considerations by the Expert Clinical Advisory Groups (ECAGs) and the Medical Devices and Human Tissue Advisory Committee (MDHTAC) in September 2023.
  - New condition to be applied to billing codes for surgical guides and biomodels to restrict the reimbursement for devices used in CMF surgery when implanting a device listed on the PL as well as limiting the quantity of billing codes payable per one clinical procedure to a maximum of 3 per episode of care.
  - Stakeholders (insurers) were also strongly encouraged to continue considering claims for reimbursement during the next few months to ensure all surgeries already scheduled for which devices have been manufactured for specific patients proceed as planned.
- Following questions and concerns raised by the hospital groups following advice at the Key Stakeholder meeting on 18 October 2023 and some sponsors, the PL Reform Taskforce released a further PHI Circular 67/23 clarifying the purpose and operation of the new condition.
- The PL reform taskforce continues to support stakeholders, specifically hospitals and sponsors, with the implementation of this condition.

Regards

s22
A/g Assistant Secretary, Prescribed List Reform Taskforce

Technology Assessment & Access Division | Health Resourcing Group
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The Department of Health 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 past and present.

I do not expect you to respond to my 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: s47F @Health.gov.au>
Sent: Monday, 23 October 2023 9:09 AM
To: s22 @Health.gov.au>
Cc: RINTOUL, Andrew <Andrew.Rintoul@health.gov.au>; PLATONA, Adriana <Adriana.Platona@health.gov.au>
Subject: Condition on billing codes for surgical guides and biomodels [SEC=OFFICIAL]

Hi s22

I see there has been an additional PHI circular put out on Condition on billing codes for surgical guides and biomodels. Would you be able to send up a couple of dot points explaining this one? I've had a few people reach out to me wanting to discuss.

Thanks
s47F

Advisor
Office of the Hon Mark Butler MP
Minister for Health and Aged Care
m: s47F
e: s47F @health.gov.au

s22

From: s22
Sent: Wednesday, 18 October 2023 8:37 PM
To: s47F
Cc: s22
Subject: FOR INFORMATION: PHI CIRCULAR - NOVEMBER 2023 UPDATE OF THE PL AND ADVICE ABOUT 10% REDUCTION AND CONDITIONS FOR SURGICAL GUIDES AND BIOMODELS [SEC=OFFICIAL]

PHI 66/23 Private Health Insurance (Medical Devices and Human Tissue Products) Rules (No. 2) 2023 | Australian Government Department of Health and Aged Care

s47F

Please see the link to the PHI circular that was published on the Department website earlier this evening. The MDHTP Rules (legislation) has been registered on the Federal Register of Legislation.

Regards

s22
A/g Assistant Secretary, Prescribed List Reform Taskforce

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Australian Government

Department of Health and Aged Care

Ministerial Submission – Standard
MS23-001597
Version (1)
Date sent to MO: 27 October 2023

RECEIVED
30 OCT 2023
Parliamentary Section

To: **Minister Butler**
Subject: **Outcome of the Post-Listing Review into Surgical Guides and Biomodels**

Critical date: 31 October 2023 – before the Private Health Insurance (Medical Devices and Human Tissue Products) Rules (No. 2) commence on 1 November 2023.

Recommendation/s:

1. That you indicate your preferred approach to the implementation of the Private Health Insurance (Medical Devices and Human Tissue Products) Rules (No.2) (the 'proposed 1 November 2023 Rules'). The following three options have been discussed with your office:

   Option 1: Continue to implement the recommendations of the Medical Devices and Human Tissue Advisory Committee (contained in the proposed 1 November 2023 Rules).

   Option 2: Delay implementation to 1 February 2024 ~~(or a date of your choosing – please indicate date)~~.

   Option 3: Do not implement the recommendations of the MDHTAC. As this will be queried by stakeholders, it would be helpful for communications that you document your reasons.

   1. **Option 1: Agreed / Not agreed / Please discuss**

   Option 2: Agreed / Not agreed / Please discuss

   Option 3: Agreed / Not agreed / Please discuss / Reasons:

2. **Note** the Department will contact all affected stakeholders with urgency (on or before 1 November) to inform them of your decision.

   2. **Note**

Signature ..... Date: 30 / 10 / 2023
Comments:

Contact Officer:	*Andrew Rintoul*	*A/g Assistant Secretary, Prostheses List Reform Taskforce*	Ph: s22 [redacted] Mob: s22 [redacted]
Clearance Officer:	*Penny Shakespeare*	*Deputy Secretary, Health Resourcing Group*	Ph: s22 [redacted] Mob: s22 [redacted]

Issues:

1. Surgical guides and biomodels are relatively new technology manufactured using 3D printing. Utilisation of and expenditure on these devices has been growing rapidly. Expenditure has increased from s47G in 2013-14, to $17,680,000 for 7488 items in 2020–21.

2. There have been disagreements among stakeholders about whether surgical guides and biomodels meet the Prescribed List (formerly known Prostheses List) (PL) criteria for listing, specifically whether these devices are explicitly designed and essential for insertion of an implantable device. Surgical guides and biomodels are listed on PL in Plastic and Reconstructive category in the subcategory for craniomaxillofacial (CMF) devices. There have been no new PL applications accepted for listing of any surgical guides or biomodels since around 2020.

3. Prior to 1 November 2023, there were no express conditions placed on any PL billing codes for surgical guides and biomodels, and hospitals could claim PL reimbursement for these devices for any procedures and for any number of devices, as soon as procedure is covered under a valid MBS item and is performed in a hospital for an insured person with appropriate cover. However it is known that insurers have been often rejecting or delaying PL claims for surgical guides and biomodels.

4. For these reasons, a post listing review was undertaken. This is the PL equivalent of a 'post market review' for medicines listed on the PBS, and the review was provided to the Medical Devices and Human Tissue Advisory Committee (MDHTAC) for consideration and recommendation, in a similar way as a medicines post-market review is provided to the Pharmaceutical Benefits Advisory Committee (PBAC) to consider and make recommendations to you.

5. Unlike the PBAC, you are not obliged by statute to follow the recommendations of the MDHTAC, and it is not a statutory body. However, it is an independent expert body, and if you choose not to follow its recommendations this will be queried by stakeholders and reasons for not implementing its recommendations will be sought.

6. The PL post listing review was conducted by an external consultant and commenced in June 2022. The review noted that surgical guides and biomodels are personalised devices used during the surgery (claimed together with an implant) but are also often used for planning and preparation prior to surgery or for manufacturing an implant (and claimed separately in additional to any implants). The review also noted that despite the surgical guides and biomodels being listed solely in the PL craniomaxillofacial subcategory, there is an increasing trend of claiming for these devices used with implants from different categories (e.g. for orthopaedic devices).

7. The post-listing review concluded that in order to meet the PL criteria for listing and remain listed, surgical guides and biomodels are required to be used for implanting/inserting an implantable device used in CMF procedures; that the procedures need to be complex; and the number of devices to be reimbursed per procedure needs to be set rather than unlimited.

8. It was agreed that representatives of the Medical Technology Association of Australia (MTAA), AusBiotech, Australian Private Hospitals Australia (APHA), Catholic Healthcare Australia (CHA), Day Hospitals Australia (DHA), Private Healthcare Australia (PHA), Members Health Fund Alliance (MHFA) would have an opportunity, on an in-confidence basis, to review and comment on the MDHTAC agenda papers prior to its meetings.

9. On 29 August 2023, the Department uploaded the MDHTAC papers (including updates on the post-listing reviews and reports) and advised the industry representatives.

10. The Department did not receive any feedback or concerns from any of the private hospital representatives about the review outcomes at this time.

11. On 7 September 2023, the MDHTAC considered the report of the surgical guides and biomodels post-listing review and recommended that:

    a. The surgical guides and biomodels that are already listed on the PL and used in CMF and oral surgery should remain on the PL. However, there was no evidence to support listing of these devices on the PL in any other category at this point.

    b. The listings for surgical guides and biomodels should be restricted to reimbursement when the device is used for CMF procedures, and the implants, for which the surgical guides or biomodels listed under the billing code may be used for the purposes of PL reimbursement, need to be specified.

    c. The number of devices that may be claimed per procedure or the total amount of benefits payable should be capped [limiting the claims to no more than 3-4 surgical guides or biomodels per procedure]. If there is a clinical need for additional devices in a single procedure, the hospital and insurer should negotiate reimbursement for the additional devices.

    d. For any other type of surgery (e.g. orthopaedic), sponsors should apply for listing of the device in that specific category and provide data to demonstrate that the device is necessary for implantation of an implantable device and lead to improved clinical outcomes.

12. MDHTAC recommended as an immediate measure that the billing codes for surgical guides and biomodels need to be specifically restricted for CMF use only to control the usage and related benefits. Accordingly, it recommended placing a new condition on all existing billing codes and any new billing codes.

13. The PL benefits for surgical guides and biomodels were set when 3D printing technology was new and expensive. The benefits have been significantly reduced under the PL reforms, but are still higher than expected. The review was planned in two stages - (1) eligibility and (2) benefits - and the second part has not yet commenced.

14. Sponsors of surgical guides and biomodels were advised about the proposed condition on 11 October 2023. All stakeholders were notified via PHI Circular 66/23 on 18 October 2023 of the outcomes of consideration of the review and about the 1 November 2023 Rules to implement the review outcomes. The PHI Circular included information on:

    a. A range of changes to be applied to the PL based on the outcomes of applications and considerations by the MDHTAC.

    b. The new condition on billing codes for surgical guides and biomodels restricting PL reimbursement for use of the device in CMF surgery when implanting a device listed on the PL and limiting the quantity of billing codes payable per single clinical procedure to a maximum of 3.

    c. Insurers were strongly encouraged to continue considering claims for reimbursement during a transitional period to ensure all surgeries already scheduled for which devices have been manufactured for specific patients proceed as planned.

15. Following questions and concerns raised by the private hospital groups following advice at a stakeholder meeting on 18 October 2023 and some sponsors, the PL Reform Taskforce released a further PHI Circular 67/23 on 20 October 2023 clarifying the intent and operation of the new condition.

16. Hospitals are concerned about the costs of devices that fall outside the restrictions which may result in private health insurers rejecting some claims for surgical guides and biomodels. Hospitals advised that they will be cancelling already scheduled surgeries after 1 November due to concerns that patients' claims will not be paid by private health insurers. This could include surgeries not within the existing PL listing criteria.

17. The Department has not been provided with any data about the projected number of scheduled surgeries, the type of surgeries and/or the period for these surgeries. The Department does not have any way of verifying the validity of these claims.

18. The 1 November 2023 Rules will come into effect shortly, and accordingly the new condition for the surgical guides and biomodels will commence, unless the MDHTP Rules are amended or you decide that they should not be made.

19. Given the stakeholders' concerns, this ministerial submission seeks your preferred approach to the implementation of the outcomes of the post-listing review into surgical guides and biomodels based on the three options below.

Option	Description	Further information (inc. risks and benefits)
Option 1: Continue with the implementation as per the Private Health Insurance (Medical Devices and Human Tissue Products) Rules (No. 2) 2023.	The condition will take effect on 1 November 2023 as previously advised. The Department may further clarify the intent and operation of the condition in PHI Circular.	The issues concerning listing of surgical guides and biomodels on the PL are well-known and have been raised by stakeholders for some time. Affected stakeholders have been consulted through the post-listing review and have been aware of expected changes. Private hospitals representatives (as well as other industry representatives) had opportunity to raise their concerns with the Department since August 2023, but did not do so. PHA, on behalf of insurers, raised concerns in August about slow progress of the review and disappointment about recommendation to leave billing codes for surgical guides and biomodels on the PL. Continuing with the condition would implement the recommendations of the independent expert MDHTAC, after its consideration of the review.
Option 2: Delay implementation to 1 February 2024 (or a date of your choosing).	The condition will not apply immediately after the Amendment Rules are made but will commence on 1 February 2024 (or a date of the Minister's choosing). The sector would be informed urgently via a PHI circular.	This will require making an Amendment Rules as soon as practicable. The Department will need to prepare a new compilation, consult with legal drafters and register the Amendment Rules on the Federal Register of Legislation. This could address concerns about the threatened cancellation of surgical procedures that have been scheduled. It will delay resolution of a long-standing issue with the incorrect PL claims for surgical guides and biomodels.

Option 3: Do not implement.	The condition will be reverted to existing PL wording.	The billing codes for surgical guides and biomodels will continue to be listed unrestricted and claimed in circumstances when these devices do not meet the PL listing criteria. This will not implement the recommendations made by the MDHTAC in regard to surgical guides and biomodels, after its consideration of the review.

20. The Department will contact all affected stakeholders with urgency to communicate your decision.

Background:

The PL Reforms were announced as part of the 2021-22 Federal Budget Measure: *Modernising and Improving the Private Health Insurance Prostheses* List.

The main objective of these reforms is to improve the value and affordability of private health insurance for consumers, by more closely aligning benefits for medical devices used in the private health sector with those applicable in the public sector.

In May 2022, as part of the PL Reforms, post-listing reviews were identified to maintain the integrity of the PL:

a. Surgical guides and biomodels
b. Metal-backed patellae
c. Spinal cord stimulators
d. Urogynaecological mesh devices (mid-urethral slings).