Review of surgical guides and biomodels currently listed on the PL: feedback and actions taken in draft report

This document collates stakeholder feedback on the draft report received between 30 Nov 2022 and 3 February 2023 and documents the amendments made to the report in response.

A substantial number of comments received relate to a small number of themes, and the report has been amended in a number of places to reflect these. These themes (and the more global changes made to address them) are detailed below.[1] Where appropriate, these changes have also been represented in the executive summary and key findings sections of the report. The following table presents all stakeholder feedback and any more specific amendments made to address each item of feedback.

Appendix A documents additional literature mentioned or supplied through this process, and AHA's response.

Appendix B supplies descriptions of key terms and clinical examples provided as an Appendix in a submission.

Simple vs Complex (SvC) theme

These comments relate to the difficulty in defining 'complex' and 'simple' surgical procedures without considering individual circumstances. While many stakeholders spoke conceptually about complex and simple surgeries and the role of surgical guides and biomodels within these (i.e. in TOR1), concerns were expressed about using these terms, procedure types, or even MBS item numbers to determine circumstances of PL eligibility. Many of these comments are closely related to the Governance theme – i.e. that further and broader consultation would be needed to define such categories, if this approach were to be considered.

The following changes address this theme in the final report:

- We have made amendments and included additional text under 1.2 ('Scope of use of surgical guides and biomodels') to reflect stakeholder views
- We have presented procedures nominated by stakeholders (and surgeons in particular) as examples of 'complex' and 'simpler' procedures, rather than as a definitive list (throughout). We have also removed these examples from key messages and the executive summary.
- We have amended the complex CMF procedure examples to include orthognathic surgery (double jaw and complex single jaw – e.g. with segmentation).
- We have amended the list of 'simpler' procedure examples to include 'simple single jaw orthognathic surgery' and 'simple orbital surgery'.
- We have added text to clarify that further work would be needed to define 'simple' and 'complex' in these contexts (Section 4.2, Criterion 4, CMF procedures).
- We have added text to list other factors (e.g. age, patient anatomy) that might affect the simplicity of a procedure.

[1] Where multiple themes are addressed, they are captured under each in the table, and marked as a 'repeat' under subsequent themes for clarity.

- We have added text in Section 1.2 ('Scope of use of surgical guides and biomodels') to note that surgical guides and biomodels may still be considered useful in simpler procedures.
- Under determination of eligibility under 'Summary of assessment of criterion 4', we have added text to suggest that caution should be applied to making blanket assumptions about the complexity of a given procedure type, as this depends on individual clinical circumstances.
- We have added a footnote where dental implants are listed as an example of simpler surgery, to note that this excludes circumstances where dental implants are placed at the same time as a more complex CMF procedure.
- We have added text to stakeholder suggestions regarding MBS item limits to capture stakeholders' concerns and need for further consultation.
- We removed specific examples of MBS items (45729 and 52375) from stakeholder suggestions regarding the restriction of circumstances in which benefits might/might not be payable.

Evidence theme

A number of issues were raised by stakeholders as part of this theme:

- A view that all surgical guides and biomodels are essentially similar (potentially using the same back-end software) and that evidence for the category is relevant to all products (i.e. limitations of using product/sponsor brands to search for evidence in our systematic review). The link between the summary of evidence and criterion 5 was therefore questioned.
- Some stakeholders questioned the applicability of randomised controlled trials/NHMRC hierarchy of evidence to this type of intervention, with surgical guides and biomodels representing both newly-adopted technology and products that are individualised and unique.
- Some stakeholders supported the notion that further/stronger evidence is required.
- Some stakeholders queried that extent to which products approved by the TGA (and PLAC) can be assumed to have proven comparative clinically effectiveness, BUT the various scenarios in which SGBs are used makes it difficult to determine if these criteria are met across all contexts or scenarios in which they are used.

To address this theme, the following amendments have been made in the final report:

- We have added an introduction to Section 2 (and restated these comments in Section 4.2 against criterion 5) to:
    - clarify our approach to identifying evidence for PL-listed products and the broader categories of surgical guides and biomodels
    - introduce key limitations to our approach as well as to existing evidence.
- We have expanded the 'Limitations' noted in Section 2.3 to include some commentary regarding the difficulty in matching evidence to PL products.
- We have added some commentary under Section 2.3 ('Strength and quality of the evidence and risk of bias') to capture stakeholders' views regarding the applicability of randomised controlled trials in the context of surgical guides and biomodels.
- We have reiterated key limitations in 4.2 under Criterion 5(i), and noted the broad support for surgical guides and biomodels in literature and consultations, at least in complex CMF procedures.

- We have added a note regarding assumptions based on TGA/PLAC approval at the end of Section 4.2, Criterion 5(i)
- We have added stakeholder views about the need for further/better evidence the need for more evidence balanced with practicalities and the need to balance with innovation and development under a new heading in Section 4.3.
- We have restated key evidence limitations in Section 5.

Limits theme

This theme captures stakeholder views on limiting PL benefits for surgical guides and biomodels (e.g. by MBS item number, number per separation or number per implant).

To address this theme, the following amendments have been made in the final report:

- We have amended text in Section 1.2 ('Increased number of products per procedure') to reflect the range of responses and incorporate suggestion of an exception process if limits were to be considered.
- We have removed the example of 2 surgical guides, 2 biomodels per procedure from stakeholder suggestions.
- We have added text to stakeholder suggestions (Section 4.3) under 'Restriction of circumstances in which benefits are payable' to reflect feedback under this theme.
- We incorporated a comment about the potential unintended consequences of any limits in Section 4.3.

Governance and consultation (governance) theme

Two key, related concepts are captured in this theme: further and broader consultation to inform any proposed changes to PL listing or eligibility criteria for surgical guides and biomodels; and ongoing governance arrangements for the PL.

To address these, the following changes have been made in the final report:

- We have noted that further consultation is needed to define 'complex' or 'simple' procedures in Section 1.2 (under 'Scope of use of surgical guides and biomodels)'
- We have addressed the need for further consultation to define appropriateness of any considered limits in Section 4.3 under 'Restriction of circumstances in which benefits are payable'.
- We added a new heading and text to stakeholder suggestions (Section 4.3): 'Review of governance arrangements', and made reference made to PLAC/MDHTAC transition (MDHTAC added to glossary).

Other changes incorporated:

- We have updated the Methodology section to reflect draft review process
- We have reworked Section 1.3 for clarity and flow, with minor additions:
    - One study notes that hospital 3D printing hubs, with centralised digital access and applications across surgical fields, will likely improve the cost-benefit ratio. However, evidence that quantifies point-of-care manufacturing costs and benefits is not available (Ansari et al. 2019).

  - Stakeholders suggested that further investigation in point-of-care manufacturing warrants government consideration (see Section 4.3).

- We have made minor clarifications and edits and throughout.
- We have updated Figure 1.
- We have reordered Table 11 by admissions.
- We have updated one figure in Table 14 to include double entry in data provided.
- We have added MBS item descriptions to Table 17.
- We amended specialty details for one surgeon consulted.
- We added a footnote to refer to surgeons' letters of support forwarded by sponsors (under TOR 1).
- We confirmed/updated TGA transition arrangements in the footnote in Section 4.2 under Criterion 1.
- We included a footnote in the background to note that 3 in-scope surgical guides are also listed in other anatomical groups on the PL.
- Under assessment against Criterion 4b, for clarity, we have removed the earlier footnote referring to PL definition of prostheses in the context of a biomodel being used in fibular free flap surgery (without another implant).
- We removed TMJ surgery from the glossary, and added TMJ to the list of abbreviations. We also updated the glossary definition of 'surgical guide' to match that in body of report.

1.1.2 Feedback sought, collated and actions taken on draft report 30th Nov 2022 to 3rd February 2023

#	Respondent category	Comment	AHA response/action
Simple versus complex (SvC) theme			
1	Peak body	'Simple' orthognathic surgery - this term has been used throughout the review but not defined appropriately. It has been implied that 'single jaw surgery' is simple. However, this fails to recognise that in some single jaw procedures, the jaw is segmented into multiple pieces and the bones cannot be accurately repositioned without some form of surgical guide.	**SvC theme**
2	Peak body	'simple' orbital surgery - what is the definition of this?	**SvC theme**
3	Peak body	Furthermore, item numbers do not accurately reflect which procedures are 'simple'. The example of orbital surgery is an excellent one as the item number which describes a single wall fracture without entrapment may be interpreted as 'simple orbital surgery'. Surgeons in the field understand that the age of the patient, the location of the orbital fracture (for example the medial orbital wall), and the anatomy of the patient (for example shape of the eye which may restrict surgical approach) determines the degree of the complexity making the MBS item number description a completely inappropriate classification system for this purpose.	**SvC theme**
4	Peak body	*Regarding stakeholder suggestion: Limiting benefits for surgical guides and biomodels to only those used in complex CMF surgeries.* Even simple single jaw surgical procedures require a 'surgical stent'. They do not require cutting guides or custom plates or biomodels. 'Surgical stents' are significantly cheaper. This error in the report has arisen because of the lack of understanding/distinction between surgical stents and cutting guides. In addition, as previously stated, even in single jaw surgery where the jaw is segmented the surgery can no longer be classified as "simple jaw surgery".	**SvC theme** Notwithstanding stakeholder comments that single jaw surgery is not always simple, surgeons did raise it as an example of a 'simpler' procedure type in which a surgical guide may not be 'essential'. A footnote has been added under 'Scope of use of surgical guides and biomodels' to capture this comment about surgical stents.
5	Clinical expert	The report promotes the conclusion that surgical guides and biomodels are not needed in alveolar ridge augmentation surgery. In this context, I would agree that surgical guides are of limited benefit in most cases, but biomodels offer very useful information. For augmentation using a custom mesh implant, the biomodel is used to confirm the proper positioning of the custom implant as they often don't 'seat' in one definite position and it can be difficult to determine if it has been positioned exactly as planned.	**SvC theme** Text has been added under 1.2 ('Scope of use of surgical guides and biomodels') to address this comment and include the example of alveolar ridge augmentation utilising custom mesh implants.

6	Clinical expert	The report promotes the conclusion that surgical guides and biomodels are not needed in single jaw orthognathic surgery. I would have to strongly disagree with this conclusion. There are many circumstances where single jaw surgery is not 'simple' and benefit significantly from custom implants with surgical guides and biomodels. A couple of typical examples come to mind. One example is segmental maxillary osteotomies where the upper jaw is divided into multiple segments and a custom surgical guide is used to accurately guide the osteotomy between the roots of teeth as well as facilitating a custom plate implant to accurately fixate the segments. Another example is for custom genioplasty, which commonly accompanies single jaw surgery and is often used to help achieve correction of complex three-dimensional asymmetries and deformities. Biomodels are also very useful in these cases as there are occasionally issues with the fit of the custom implants and the biomodel is used to confirm positioning as well as identifying areas of bony interference affecting the positioning of the implant.	**SvC theme**
7	Sponsor	We request the procedures considered 'simple' be included in an objective and measurable review (i.e. through evaluation and or collection of clinical evidence), rather than removal following opinions of a select, small number of surgeons.	**SvC theme** (see also **Governance theme)**
8	Sponsor	To ensure improvement in interpretation of understanding eligibility, the suggestion to reference surgery type, i.e. "simple vs complex" as the only determinant for SGB inclusion or exclusion with these descriptions is problematic. These adjective based terms hold ambiguity on their own in the absence of a PICO context.	**SvC theme**
9	Peak body	*Regarding complex clinical procedures:* Use of biomodels and guides are important also in cases of: • craniofacial/congenital birth defects (e.g. craniosynostosis conditions) • Cranial vault reconstruction and cranioplasties – these are very complex procedures usually in patients with congenital malformations. This category appears to have been completely overlooked in this review. Orthognathic surgery- jaw surgery with segmentation into multiple pieces, including single jaw surgery with segmentation is a complex procedure (this has been missed in the review under the complex procedure section) and should meet the criteria for the use of the guides and models.	Cranial vault reconstruction and cranioplasties and example of craniosynostosis conditions have been added to Table 2 and the list of complex CMF procedures in which surgical guides and biomodels were reported to be essential (in assessment of criterion 4). **SvC theme**

10	Peak body	[We] principally support AHAs assessment of SG&Bs eligibility against criterion 4b, in that under appropriate clinical circumstances these devices are essential to and specifically designed as an integral single-use aid for implanting the primary prosthesis. - [We] agree with AHAs list of complex CMF procedures in which they determine this criterion to be met. - [We] believe that of the list of 'simple' CMF procedures in which AHA determine this criterion to not be met, that single jaw orthognathic and orbital floor surgeries are inaccurately placed. Whilst possibly being considered as not as complex of a procedure, the devices associated with single jaw orthognathic and orbital floor surgeries are still essential to and specifically designed as an integral single-use aid for implanting the primary prosthesis. [We] agree that this criterion is not met for SG&Bs when used in procedures that do not involve implantation of a prosthesis.	**SvC theme**
11	Sponsor	*Responding to stakeholder recommendation: Clarifying PL eligibility criteria (and giving examples of eligible and ineligible types and usage of surgical guides and biomodels* MBS codes and the relevant patient population will avoid unforeseen patient exclusion if using simplistic descriptive terms of surgery types, for example single jaw surgery is not "simple" by default; surgeons use SGB for these procedures due to defined patient variables, ensuring consistent techniques and surgical treatment approaches eg. orthognathic treatment.	**SvC theme**
12	Sponsor	We challenge the position taken that surgical guides and biomodels for 'simple' procedures' do not meet the criteria.	**SvC theme**
Limits theme			
13	Peak body	[We] do not support placing limits, at this time, on the benefits payable through the PL by any of the mechanisms proposed by the Draft Review: •Specifying the MBS items for which surgical guides and biomodels are eligible for benefits through the PL mechanism. •Limiting the number of surgical guides and biomodels for which a PL benefit is paid per separation. Additional consultation with surgeons is suggested to identify an appropriate limit. •Considering alternative approaches to listing of benefits, such as stratified or tiered approaches.(Page 10)	**Limits theme**

14	Peak body	[We] disagree that limitations should be placed on the number of surgical guides and biomodels for which a PL benefit is paid per separation. The very nature of these devices is to provide personalised solutions based on the patient specific requirements. As part of the private health value proposition a surgeon should be able to utilise any number of SG&Bs as appropriate for the patient being treated. Placing limits based on average utilisation will likely lead to either patients receiving sub-optimal care with surgeons bound by limits or patients having increased out-of-pocket expenses.	**Limits theme**
15	Peak body	*Responding to stakeholder suggestions: Placing limits on the benefits payable through the PL* The first action should be to limit the use of biomodels and surgical guides for complex CMF procedures through specifying the MBS items for which surgical guides and biomodels are eligible for benefits through the PL mechanism. This should be done immediately, and the review report should be able to nominate the relevant item numbers which match the described procedures on page 69 of the draft report. This action should be taken for the 1 March 2023 Prostheses List update.	**Limits theme** We have added in the discussion of restrictions in Section 4.3 to note that while there was significant in-principle support MBS item-based restrictions from some stakeholders, it was not unanimous and not without significant caveats. And, that further consultation with clinical experts would be needed to inform such limits. (see also **Governance theme**)
16	Peak body	*Responding to stakeholder suggestions: Placing limits on the benefits payable through the PL* Limiting the number of surgical guides and biomodels for which a PL benefit is paid per separation is supported in the short term, and [we] recommend that that limit be set at the number of plates used (one plate allows for one biomodel and one surgical guide. This already adds over $3000 to the cost of the procedure. There is no justification to use multiple models for a single plate (noting that a biomodel or surgical guide may come in separate parts – these parts should not be billed separately).	**Limits theme**
17	Peak body	[We] support the generation of more economic and clinical evidence to support future policy decisions regarding the use, limitations set and pricing of surgical guides and biomodels. In the absence of this information [we] urge government to not make decisions that could limit the number or choice of these items used by medical practitioners. The Draft Review clearly identifies that these items are growing in use and popularity by surgeons. This is a developing area of prostheses use and should be supported unless there is more definitive evidence of reduced clinical outcomes or excessive costs.	**Limits theme** (see also **Evidence theme**)

18	Peak body	[We] strongly oppose limitations being placed on the number of surgical guides and biomodels. The very nature of these devices is to provide personalised solutions to specific patient requirements. As part of the private health value proposition a surgeon should be able to utilise any number of SG&Bs as appropriate for the patient being treated. Placing limits based on average utilisation will likely lead to either patients receiving sub-optimal care with surgeons bound by limits or patients having increased out-of-pocket expenses.	**Limits theme**
19	Sponsor	*Responding to stakeholder recommendation: Placing limits on the benefits payable through the PL* Implantation of any medical technology is at the discretion of the treating surgeon. Capping and limiting funding is plausible if aligned to the surgeon societies' recommendations, knowing that for any seriously complex patients warranting technology beyond an advised limit will be managed by the exceptional requests process and possibly require prior PHI approval. If all surgeons are informed and are provided the opportunity to submit feedback to this recommendation, sponsors will oblige their decision. Patient co-payment or hospital payment beyond funding will occur, therefore ensuring the limit doesn't create an unforeseen consequence with reduction in patient access, or the risk of sub-optimal treatment, this could be considered and result in determining a reasonable limit.	**Limits theme** (see also Governance theme)
20	Sponsor	*Responding to stakeholder recommendation: Placing limits on the benefits payable through the PL* We do not agree with limiting the number of surgical guides and biomodels for which a PL benefit is paid per separation without full society consultation. Sponsors will oblige the decision as advised with full disclosure to all members of the relevant surgical societies being proactively engaged by the Department prior to any final decision.	**Limits theme** (see also Governance theme)

21	Sponsor	Below are the MBS item numbers which the Review identified as having the highest biomodel and guide usage. For each MBS item we have provided the clinical knowledge we have gained from the surgeons who use these guides: OSTEOTOMY/JAW CUT utilisation: Surgical Guides: 1xcutting guide is required for the bone and in many cases 1xguide for the teeth. Depending on surgical complexity, the surgeon may select 1 and 3 guides. Most often only 1 guide is used, but there are complex cases where 3 are required. Biomodels: 2xmodels show the surgeon where to cut/drill, the other 2xmodels show the surgeon the post-operative position. 45729 -Bilateral osteotomy case: Average procedure will use 3x GUIDES + 4x BIOMODEL S45744 –Bilateral osteotomy: 4x GUIDES + 4x BIOMODELS 45738 –Bilateral osteotomy: 5x GUIDES + 4x BIOMODELS 45752 + 52375 + 52363 –Bilateral osteotomy: 6x GUIDES + 4x BIOMODELS 52357 –Single jaw osteotomy: 2-4 BIOMODELS, 1-3 GUIDES depending on the complexity of the surgery 45841 –Alveolar ridge augmentation: this is cutting the patients jaw, it's still an osteotomy and requires a guided cut to ensure correct leveling of the bone. For these cases and depending on the complexity of surgery, 1-4 biomodels, 1-6 guides are required.	**Limits theme**

22	Clinical expert	*Regarding stakeholder recommendations on placing limits on items:* There will be usually two surgical guides required for major head and neck surgery – a resection guide and a reconstruction guide. However, it is not always possible to have a connected guide for the resection due to anatomical limitation and therefore two cutting guides (left and right) will have to be fabricated. Could I request that the review team considers this and allow up to three surgical guides for complex CMF procedures? With regards to biomodels, may I request the review team to consider the following for each specific case: <u>Cases with custom titanium reconstruction plate</u> 1x biomodel of bone graft template with plate for fitting into the defect and templating of soft tissue 1x biomodel of resected jaw to fit the bone flap ensuring good fit of bone edges to actual mandible. 1x biomodel of fibula bone to ccorrelate fit of surgical guide. <u>Cases with prebent stock titanium plate</u> 1x biomodel of reconstructed jaw to prebend a stock plate 1x biomodel of resected jaw to fit the bone flap ensuring good fit of bone edges to actual mandible. 1x biomodel of fibula bone to ccorrelate fit of surgical guide. <u>Cases of a jaw in a day</u> 1x biomodel of bone graft template with plate for fitting into the defect and templating of soft tissue 1x biomodel of resected jaw with the opposing teeth to fit the bone flap and dental prosthesis against prior to inset ensuring good fit of the flap and dental prosthesis 1x biomodel of fibula bone to correlate fit of surgical guide.	**Limits theme**

23	Clinical expert	*Regarding stakeholder suggestion on placing limits on items:* The goal of the review should be to prevent unnecessary costs. To limit the number of guides and models is an oversimplification that may have the opposite effect in some cases where having additional guides and models makes the surgery faster and/or more precise. It is common that more than two guides are required in the case of jaw reconstruction for oncology with dental implants where one guide is used to cut the jaw, one guide is used to cut the donor bone (e.g., the fibula), one guide is used to place the dental implants, and one guide is used to hold the upper and lower jaw in the correct occlusion. If the procedure was limited to two guides, then surgeons would divide the operation into two separate procedures (anaesthetics) to allow the use of additional guides. This would result in additional health care costs, increase complications, reduce patient quality of life, and inaccuracies that may require correctional surgeries. There are similar instances where more than two biomodels are required.	**Limits theme**
24	Peak body	*Regarding stakeholder suggestion: linking MBS item numbers to product utilisation* The linkage of MBS item numbers to surgical guides and biomodels is a blunt instrument. This type of approach has historically failed. The MBS item numbers were designed with the intention of defining classes of medically relevant procedures; linking emerging technologies to these categories is arbitrary and restrictive as it is an oversimplification of the way surgery is performed. It restricts the ability of new innovations and emerging technologies in a rapidly and evolving field and does not future-proof our system particularly when new applications emerge, associated costs are reduced and local hubs become established.	**Limits theme**
Evidence theme			
25	Peak body	[We] also support increasing the health evidence base across the private health sector and particularly for PL or PL-like items. This includes economic evaluation (including looking at efficient prices for items) but we believe this needs to be balanced with the requirement to invest in innovation and development.	**Evidence theme**

26	Peak body	AHA have stated that in establishing the evidence base for SG&Bs their review of peer-reviewed literature was limited to systematic reviews and meta-analyses as well as publicly available and supplied grey literature, and other relevant documents. [We] propose that limiting the review of literature to systematic reviews and meta-analyses does not constitute a comprehensive clinical evaluation.	**Evidence theme** Our evidence strategy was 2-fold: to examine the specific products on the PL (where possible) and to examine the broader body of evidence by summarising synthesised literature. We note in the report (section 2.4) that the latter is not intended to be a systematic review of published literature, and does not represent a complete or comprehensive summary of the literature available.
27	Peak body	AHA have noted that the literature frequently suggests that the use of 3D technologies, including SG&Bs produces results that are not inferior to 'conventional' techniques and may have additional benefits. [We] propose that this statement directly demonstrates SG&Bs adherence to criterion 5, in that comparative clinical effectiveness to either alternative products on the Prostheses List or alternative treatments (i.e. conventional techniques) has been established.	**Evidence theme**
28	Sponsor	We acknowledge that the volume of clinically published data is limited, and that there is a lack of randomized controlled-trials (RCT). Our experience is that in a surgical setting where a surgeon must make a clinical choice for their patient, there are very few surgeons who will put aside their first choice of treatment for a patient, and opt to randomise the patient to an intervention or control treatment. Patients' who are treated using our craniomaxillofacial guides and biomodels typically require very complex surgeries and are not suitable candidates for randomising in a clinical study context. This limits the ability to provide RCT evidence, and can in part explain the reason for a higher volume of real world evidence (RWE) in the form of case control and cohort studies.	**Evidence theme**
29	Peak body	AHA have also noted a lack of randomised controlled trials (RCTs) in the evidence base for SG&Bs, [we] propose that the applicability of RCTs in reviewing SG&Bs is limited given (1) each device is personalised, and each patient has specific requirements and (2) the potential for selection and detection bias.	**Evidence theme**
30	Peak body	The Prosthesis List draft report references the use of table 24 NHMRC (2009) Level of evidence. The use of the levels of evidence in surgical practice has well been documented and the article below provides good contextual background about the development of surgical guidelines in the context of emerging technologies: Evidence in surgery- Levels and Significance, Sandeep Kumar, Indian Journal of Surgery volume 81, pages 307–316 (2019)	**Evidence theme**

31	Clinical expert)	*In response to the literature review in TOR 2*: It is important to understand the usage of word "ProPlan" in the studies included for the systemic review. Proplan was originally registered by Synthes (later DePuy Synthes owned by Johnson and Johnson) to describe their virtual surgical planning production partnership with Materialise. This was later changed to 'Tru-Match'. This product was compared with both traditional (non-virtual surgical planning) surgeries and in-house (point of care) virtual surgical planning using by Mazzola et al. The software produced by Materialise to conduct virtual surgical planning is known as ProPlan CMF. Many commercial providers in Australia who have products listed on the PL use this software. Hospital based (point of care) manufactures also use Materialise ProPlan CMF software as this is the only software that has regulatory approval. Until another virtual surgical planning software obtains regulatory approval and becomes available commercially, most of the industry will continue to use Materialise ProPlan CMF software.	**Evidence theme**
32	Peak body	*Regarding TOR 4 Criterion 5(i) clinical effectiveness* The report concludes that there is insufficient evidence to support that criterion 5(i) is met. Based on the methodology adopted (section 2) and its limitations, it is unclear if such a conclusion can be drawn. Drawing this type of conclusion would certainly be inconsistent with current international practice and standards of care in this field. There is a distorted and limited literature review focusing on the commercial company products rather than the application of these technologies to surgical practice and the impact they make. The assumption that every single product "brand" using the same technology must be separately proven with respect to clinical effectiveness is an erroneous one. The back-end technology for these products is confined to a limited number of generic platforms.	**Evidence theme**

33	Peak body	*Regarding TOR 2:* Using product specific search terms alone is a flawed search methodology for finding evidence for the use of these guides and biomodels. The search terms need to be broadened to include surgical procedures that utilise these technologies. The former approach fails to capture a significant number of the publications that support the use of these surgical tools. This is because the back-end technology used by the commercial companies, for software and CAD/CAM manufacturing is essentially the same. The companies' brand does not provide a unique type of guide or biomodel. By way of example, a list of articles which are considered key articles in orthognathic surgery (alone) using these guides and biomodels has been attached. This list is not exhaustive and was put together as an example. It represents some key recognised articles by surgeons in the field and it is unclear if these articles were altogether missed in the literature search or excluded from the report. The list provided includes the following two RCTs. According to the current draft report no RCTs exist to support the use of guides and biomodels: Excluded articles were not listed in the Prosthesis List draft report and hence no comments can be made regarding this.	**Evidence theme** Articles reviewed for potential inclusion (Appendix A in this document). Report now refers to a paucity of randomised controlled trials, rather than a lack.
34	Peak body	[We] disagree with AHAs assessment of SG&Bs eligibility against criterion 5, in that there is currently insufficient evidence to determine if this criterion 5. [We] also suggest that this statement in contradictory to outcomes presented by AHA under ToR 2 – Evidence base. - Under ToR 2 AHA have statement that clinical literature supports the use of SG&Bs across a range of contexts including oral and CMF applications, orthopaedics, cardiovascular surgery, and ENT surgery. AHA additionally noted that the literature frequently suggests that the use of 3D technologies, including SG&Bs produces results that are not inferior to 'conventional' techniques and may have additional benefits. - [We] propose that the above statements directly demonstrate SG&Bs adherence to criterion 5, in that comparative clinical effectiveness to either alternative products on the Prostheses List or alternative treatments (i.e., conventional techniques) has been established. - Additionally, all these devices have historically been comprehensively reviewed, assessed, and approved by the Plastics and Reconstructive PoCE and PLAC in being comparatively clinically and cost effective. Further, all these devices have been evaluated by the TGA in being comparatively safe and effective.	**Evidence theme**

35	Peak body	[We] also strongly support improving the evidence base and support for innovative new PL and PL-like products being developed and used to improve patient health outcomes. [We] have called for the reforms to the PL to be used not just to deliver efficiencies in price, but to improve the evidence supporting prostheses use and therefore the clinical effectiveness of practice. Medical practitioners have been the leaders in generating this evidence base. It was the Australian Orthopaedic Association that established the National Joint Replacement Registry (AOANJRR), which has been operating nationally for more than 20 years collecting information on hip, knee, shoulder, elbow, wrist, ankle and spinal disc replacement from all hospitals in Australia undertaking joint replacement surgery. This registry has saved the health system hundreds of millions of dollars by providing information on the performance of prostheses to clinicians and therefore driving change in utilisation. [We] hope that, as part of the next phase of these reforms, the Government takes this opportunity to support increasing the evidence base for prostheses use. The need for this increase in evidence is highlighted by this post-listing review process.	**Evidence theme**
36	Sponsor	The reports states that .."some stakeholders–including surgeons and private health insurance representatives –reported that use of surgical guides and biomodels does not represent value for money for low-complexity procedures." Whilst we understand there were 13 surgeons who made statements such as this, we challenge the conclusion that based on the opinion of a limited number of individuals that a range of surgical indications can be restricted from using surgical guides and biomodels. Health care decision making should never be based on opinion, and we believe that clinical evidence should be sought prior to this decision being made final.	**Evidence theme** **(see also Governance theme)**
17 **(repeat)**	Peak body	[We] support the generation of more economic and clinical evidence to support future policy decisions regarding the use, limitations set and pricing of surgical guides and biomodels. In the absence of this information [we] urge government to not make decisions that could limit the number or choice of these items used by medical practitioners. The Draft Review clearly identifies that these items are growing in use and popularity by surgeons. This is a developing area of prostheses use and should be supported unless there is more definitive evidence of reduced clinical outcomes or excessive costs.	**Evidence theme** Final sentence included in quote under new heading ('Further and stronger evidence') in Section 4.3. (see also **Limits theme**)
Governance theme			
37	Peak body	We support as a general principle collaborating with the medical profession as the relevant experts whenever appropriate and we again call for this to be built into the future governance arrangements for the whole scheme. Accordingly, we strongly support the following recommendation arising from this Draft Review: •Collaborating with surgeons, industry representatives and sponsors when considering future changes. (Page 82)	**Governance theme**

38	Peak body	[We] agree strongly with both the intent and with the specific statement: Further consultation may be required to identify the appropriate limit in different clinical circumstances. (Page 82) Any discussion of limits in terms of benefits or numbers may impact clinician choice and patient clinical outcomes. This issue requires the collection of further information and evidence and appropriate consultation with the medical profession (including referral to CIRG or another clinical committee) before any decision can be made.	**Governance theme**
39	Peak body	This review highlights the need for ongoing clinical expertise to be available to support the work of both the PL reforms and the ongoing management of the PL into the future. This clinical advice needs to be built into the future governance arrangements for the PL and must be appropriately resourced and funded.	**Governance theme**
40	Peak body	[We] support addressing any eligibility issues that arise in the context of concurrent work being done to regroup products currently listed on the PL. The suggestion from the Draft Review highlights the need for a fit for purpose clinical group to be built into the governance arrangements for the PL. [We] welcome the 17 January 2023 announcement increasing the number of clinical experts through the new Medical Devices and Human Tissue Advisory Committee (MDHTAC). However, we understand that the role of this committee will be to provide recommendations and advice about the comparative clinical effectiveness and cost effectiveness of medical devices and human tissue products on the prostheses list, and the benefits payable by private health insurers. This does not seem to cover broader eligibility and potential restriction issues like the ones raised by this review. Accordingly, in the absence of the new governance structure being in place, we call on the eligibility issues identified in the Draft Review to be referred to and reviewed by the PL Clinical Implementation Reference Group (CIRG).	**Governance theme**
7 **(repeat)**	Sponsor	We request the procedures considered 'simple' be included in an objective and measurable review (i.e. through evaluation and or collection of clinical evidence), rather than removal following opinions of a select, small number of surgeons.	**Governance theme** (see also **SvC theme**)
15 **(repeat)**	Peak body	*Responding to stakeholder suggestions: Placing limits on the benefits payable through the PL* The first action should be to limit the use of biomodels and surgical guides for complex CMF procedures through specifying the MBS items for which surgical guides and biomodels are eligible for benefits through the PL mechanism. This should be done immediately, and the review report should be able to nominate the relevant item numbers which match the described procedures on page 69 of the draft report. This action should be taken for the 1 March 2023 Prostheses List update.	**Governance theme.** (see also **Limits theme**)

19 (repeat)	Sponsor	*Responding to stakeholder recommendation: Placing limits on the benefits payable through the PL* Implantation of any medical technology is at the discretion of the treating surgeon. Capping and limiting funding is plausible if aligned to the surgeon societies' recommendations, knowing that for any seriously complex patients warranting technology beyond an advised limit will be managed by the exceptional requests process and possibly require prior PHI approval. If all surgeons are informed and are provided the opportunity to submit feedback to this recommendation, sponsors will oblige their decision. Patient co-payment or hospital payment beyond funding will occur, therefore ensuring the limit doesn't create an unforeseen consequence with reduction in patient access, or the risk of sub-optimal treatment, this could be considered and result in determining a reasonable limit.	**Governance theme.** (see also **Limits theme**)
20 (repeat)	Sponsor	*Responding to stakeholder recommendation: Placing limits on the benefits payable through the PL* We do not agree with limiting the number of surgical guides and biomodels for which a PL benefit is paid per separation without full society consultation. Sponsors will oblige the decision as advised with full disclosure to all members of the relevant surgical societies being proactively engaged by the Department prior to any final decision.	**Governance theme.** (see also **Limits theme**)
36 (repeat)	Sponsor	The reports states that .."some stakeholders–including surgeons and private health insurance representatives –reported that use of surgical guides and biomodels does not represent value for money for low-complexity procedures." Whilst we understand there were 13 surgeons who made statements such as this, we challenge the conclusion that based on the opinion of a limited number of individuals that a range of surgical indications can be restricted from using surgical guides and biomodels. Health care decision making should never be based on opinion, and we believe that clinical evidence should be sought prior to this decision being made final.	**Governance theme** (see also **Evidence theme**)
Other feedback actioned			
41	Peak body	[We] would like to highlight that removed items are clinically important and alternative funding models must be in place before removal to ensure they are still available for use by medical practitioners and can contribute to improving patient outcomes. [We] do not support the development of individual reviews removing items from the PL without them being included in any broader processes (such as the new funding arrangement being developed for general use items scheduled to be removed from the PL) to ensure adequate, ongoing funding.	Need for alternative funding models, should surgical guides and biomodels be removed from the PL, noted under new heading 'Further and stronger evidence' in Section 4.3.

42	Peak body	Post-listing reviews need to find the balance in acknowledging that that early stages of developing medical innovation can cost more but can also deliver increased efficiency and/or improved clinical outcomes into the future.	Quote added under new heading 'Further and stronger evidence' in Section 4.3.
43	Peak body	[We] would also like to reiterate our advice that items being removed from the PL are not being removed because they are not clinically appropriate and efficacious. Alternative funding and other arrangements for the future management of such items is key to maintaining clinician choice and patient outcomes.	Need for alternative funding models, should surgical guides and biomodels be removed from the PL, noted under new heading 'Further and stronger evidence' in Section 4.3.
44	Peak body	AHA have stated that the utilisation of SG&B has risen significantly over recent years and that as result private health insurers have had to pay more for these devices year-on-year, and in turn this cost is generally passed on to consumers through increased private health insurance premiums. [We] believe it is important to highlight that as per the Australian Prudential Regulation Authority (APRA) Quarterly Private Health Insurance Statistics for June 2022 of the $AUD26 billion in expenditure by private health insurers, around $2.25 billion is spent on medical devices via the Prostheses List, representing about ~8% of total contributions. As stated in the AHA review in 2020-21 SG&Bs accounted for $17.7 million, representing only 0.79% of total Prostheses List expenditure and 0.07% of total PHI expenditure. Therefore, the claim that the increased utilisation of SG&B is leading to increased premiums is inapt, as at 0.07% of total expenditure these devices have negligible impact on premium increases.	We have clarified in the report that these are the published views of PHA. Statemt in consumer summary softened to note that increased claims could affect private health insurance premiums. APRA's Quarterly Private Health Insurance Statistics were not analysed in this review.
45	Sponsor	We note commentary from the PHI stakeholder referencing generalised figures associated with SGB utilisation and associated increased cost has a direct correlation with PHI premium increases. This sub-category of implant cost as noted by AHA represents less than 0.1% of total PHI expenditure1. We suggest per the APRA reference, SGB's are not contributing to excessive premium increases, nor PHI increased cost.	As above, we have clarified in the report that these are the published views of PHA.
46	Peak body	Additionally, [we] note that 'significant increase' is a subjective statement and should not be associated with 'over' or 'incorrect' utilisation. As stated in this review the majority of utilisation is delivered in a clinically appropriate setting and deemed clinically relevant by clinicians. Therefore, the 'significant increase' in utilisation is primarily associated with the adoption of innovative technology by the surgeon community based on the clinical merit and effectiveness of the devices. As such [we] propose that the only remaining question is how and what measures should be implemented to ensure that the ongoing utilisation of SG&Bs listed of the Prostheses List is in alignment with; (1) the clinical indications of the primary prothesis, (2) the intention of the approved PL groups (i.e., plastic and reconstructive vs. orthopaedic) and (3) the patient specific requirements as decided by the surgeon.	Replaced significant with substantial and provided an example in consumer summary. In TOR 3 where increases are reported they are quantified by percentages.

47	Peak body	Whilst surgeons and peak clinical bodies have reported that SG&Bs are less useful in less complex procedures, [we] maintain that this does not mean these devices present no clinical benefit in these cases and whilst utilisation is in scope of the device indications and in alignment with PL eligibility then there is a continued role in clinical practise.	Note added in ToR 1 where simpler procedures are discussed. However, when considering eligibility criteria, eligible surgical guides and biomodels are 'essential', rather than 'useful' or 'widely used'.
48	Peak body	AHA's definition of surgical guides is that these technologies are "patient-specific tools that are not implanted but designed to transfer the planned surgical and prosthetic components of a procedure to the actual surgery (Poitros and Pena 2016). They are used to guide the precise cutting of bone or drilling of holes as needed for implantation (Francoisse et al. 2020). Types of surgical guides include splints and plates." Whilst [we] broadly support the AHA definition it is important to note that Poitros and Pena 2016 reviewed CAD/CAM surgical guides for dental implantology. In the context of dental implant surgery, it is correct to say that the guides are not implanted, as they sit on the dentoalveolar bone for a few minutes. However, surgical guides used for craniomaxillofacial surgery are temporarily implanted by screw fixation to facilitate the cutting of osteotomies and predrilling of patient-specific plate aligned screw holes. Surgical splint guides are often wired in place and, in for some indications for e.g., segmental maxillary osteotomies, may remain in position after the surgery. To support the formulation of definitions and clearly define these devices [we] have included an overview of associated technologies in Appendix A.	Definition of surgical guide amended in Section B.1, and footnote added to say surgical guides are often temporarily fixed during surgery (and in some cases, may remain in place afterwards). Added separate definition for splints to the glossary.
49	Sponsor	[We] caution the definition proposed for surgical guide as not implanted, this is technically incorrect and for specific CMF procedures, surgical and splint guides can be implanted and remain implanted.	As above, definition of surgical guide amended in Section B.1, and a footnote added to say surgical guides are often temporarily fixed during surgery (and in some cases, may remain in place afterwards).
50	Peak body	As mentioned in the 'General Comments' [we] note that 'significant increase' is a subjective statement and should not be associated with 'over' or 'incorrect' utilisation. As stated in this review the majority of utilisation is delivered in a clinically appropriate setting and deemed clinically relevant by clinicians. Therefore, the 'significant increase' in utilisation is primarily associated with the adoption of innovative technology by the surgeon community based on the clinical merits and effectiveness of the SG&Bs as well as the demonstrated clinical effectiveness of patient specific implants.	Replaced 'significant' with 'substantial' This statement is made in the context of utilisation data to evidence the claim. The report acknowledges the appropriate reasons for growth in use of surgical guides and biomodels.
51	Peak body	Surgical guides and biomodels are listed under the plastic and reconstructive product category and [we] agree that utilisation outside of this category (i.e., orthopaedics) should be minimised to as close to zero as possible.	Added recommendation in Section 4.3 to limit benefits to MBS items in specific categories (e.g. plastic and reconstructive).

52	Peak body	[We] believe that placing 'average' limits for ease of administration and removing the surgeon's ability to exercise their clinical judgement, will result in cases that require additional guides or models to either self-fund or, more likely, move to the public system. This is especially the case for Category 1/2 cancer and trauma where the wait lists are not as much of a barrier such as those for Category 3. There are also a large number of private head and neck cancer patients being treated in the public system due to the complexity of care and post op observation required. Removal or limitation of reimbursement for models and guides would simply shift the funding burden to the public system, not remove it.	Text added to Section 4.3 (stakeholder suggestions) to note need for alternative funding and avoidance of unintended consequences.
53	Peak body	[We] disagree that there is a need to conduct an economic analysis to review the benefit amounts specified on the PL. As stated above, this review has demonstrated that SG&Bs adhere to the PL eligibility criteria and as such the pricing mechanism for these devices is that of all PL benefit groups, the average weighted public price methodology.	'Most' added to statement re economic analysis under 'Costs may outweigh benefits for simple procedures', Section 1.2, i.e: "**Most** stakeholders suggested that further cost analyses, including examination of manufacturing costs, are needed to clarify this issue." Otherwise, pricing mechanism is out-of-scope.
54	Peak body	[We] disagree that there is a need or even mechanism to consider alternative approaches to listing of benefits. This review has demonstrated that SG&Bs adhere to the PL eligibility criteria and as such the pricing mechanism for these devices is that of all PL benefit groups, the average weighted public price methodology.	We have added a note to clarify that some stakeholder suggestions listed in 4.3 fall outside the scope of the review, and may not be feasible under current PL mechanisms.
55	Sponsor	*Responding to stakeholder recommendation: Clarifying the role of surgical guides and biomodels as individual products and as elements of 'kits' or bundles currently listed on the PL* The principle of PL listing is by unique component with aligned PHI funding only for implanted prostheses that meet the eligibility criteria, SGB meet this criterion. The configuration of SGB supply to the hospital whether in kit format or separate item should not confuse implantation and subsequent PHI reimbursement claims. We propose that catalogue numbers representing supply by kit format also detail catalogue number by content, from which implantation is currently recorded in the operation record for each surgical procedure. The catalogue numbers recorded in the PLMS should only reflect the implanted technology, not the ordering numbers for supply – this should resolve this concern.	No action required - presents opinion of documentation of item usage. However, we have edited the suggestion for the department regarding kits to read (added text in bold): "Clarifying the role of **and pricing structures for** surgical guides and biomodels **supplied** as individual products and as elements of 'kits' or bundles currently listed on the PL."
56	Sponsor	*Responding to stakeholder recommendation Conducting an economic analysis* We propose the current PL reform approach to benefit setting by using an IHACPA analysis from the public sector. This will identify if there is a discrepancy. This is the only solution the Department should consider maintaining consistency across Part A for PL reform.	IHACPA review referenced in footnote as an example in stakeholder recommendations and in economic analysis recommendation.

57	Sponsor	We also seek feedback on the level of experience and type of practice of the surgeons who were interviewed (i.e. are they currently using biomodels and guides?) and was the surgical society ANSZAOMS consulted?	ANSZAOMS is on the list of stakeholders consulted. We have added text to the methodology section (B.1.3.2) and Appendix A to note that the department provided AHA with a list of stakeholders to approach for participation in this review.
58	Sponsor	We recommend that procedures considered to be 'simple' continue to be funded under the PL whilst clinical evidence is collected, including patient-reported outcome measures which we note are not a part of the clinical evidence currently. •Simple orthognathic surgery (single jaw) •Orbital surgery •sinus lift procedures •alveolar ridge augmentation •dental implants (e.g. following tooth extraction)	Our determination regarding simpler procedures is based on current eligibility regarding whether or not surgical guides and biomodels are essential to the implantation. The report notes that stakeholders frequently reported that these products were ver useful in simpler procedures. We also note under stakeholder suggestions that funding structures needed to be considered in the light of any delisting/limiting circumstances.
59	Peak body	*Clarifying PL eligibility criteria (and giving examples of eligible and ineligible types and usage of surgical guides and biomodels)* Supported. This clarification should include a clear definition of diagnostic items, which are likely to include biomodels. The clarification should also include the difference between devices eligible for the Prostheses List and items which are surgical tools, and thus ineligible. The review does not discuss why biomodels are not diagnostic tools, nor why surgical guides are not surgical tools. In the absence of clear justifications for differences, to avoid indication creep any remaining models should be moved to Part C or packaged with biomodelled plates.	Added to stakeholder suggestions (Section 4.3) under 'Clarification of eligibility criteria'.
60	Peak body	*Responding to stakeholder suggestions: Addressing some of the eligibility issues raised in the context of concurrent work, to reorganise or recategorise products currently listed on the PL* Supported in principle, noting that remaining items may need to move to Part C or packaged with biomodelled plates.	Added to stakeholder suggestions (Section 4.3) under 'under 'Review of benefits and claiming arrangements'.

61	Peak body	*Responding to stakeholder suggestions: Clarifying the role of surgical guides and biomodels as individual products and as elements of 'kits' or bundles currently listed on the PL* Supported. There will be significant value in rolling up benefits into a kit where the biomodels and guides (which are mirror images of the plates) are supplied as part of the kit with the biomodelled plate. This addresses the issue of a direct connection between the biomodels/guides and the primary item. The value will be maximised if the economic evaluation considers the total package – currently there is a very high premium paid for biomodelled plates, and consumers arguably pay twice with high prices for surgical guides and biomodels.	New suggestion added to stakeholder suggestions (Section 4.3) under 'Review of benefits and claiming arrangements'.
62	Peak body	*Responding to stakeholder suggestions: Placing limits on the benefits payable through the PL* Alternative approaches to benefits should be considered as part of the economic analysis to review benefits. For example, it is particularly galling to see plastic models receiving higher total rebates than the implanted devices – there is merit is considering a percentage cap.	Added to stakeholder suggestions (Section 4.3) under 'Review of benefits and claiming arrangements'.
63	Peak body	*Responding to stakeholder suggestion: Investigating areas where it is suggested that benefits are being claimed inappropriately* It is unclear what such an investigation would achieve. The inappropriate claiming of biomodels and surgical guides is allowed by the interpretation of the current legislation by the Department of Health and Ageing and thus requires a policy fix. It appears that at least one sponsor may have provided misleading information to the department to obtain financial benefit, by providing incorrect information in their application for benefits through the Prostheses List. Certainly the market segment this sponsor has been active in does not match in any way the information provided when seeking listing. [We] do not have access to the full documentation to offer a view as to if a crime has been committed under ss134-135 of the Criminal Code.	In Section 5, suggestion expanded to read: Investigating**, and taking action to address,** areas where it is suggested that benefits are being claimed inappropriately. (bold represents new text)

64	Peak body	*Responding to stakeholder suggestion: Conducting an economic analysis to review benefits* Supported. In addition to the benchmarks proposed, [we] recommend that the MBS schedule fee for the procedure be considered – it is troubling to health funds that the remuneration for such complex procedures is weighted so heavily to devices rather than skilled surgeons, and this does not appear to match the value provided. For legitimate usage in complex CMF procedures, the cost of a biomodel, a surgical guide and a biomodelled plate are very high indeed compared to cost of manufacturing and are well in excess of the medical rebate costs. Bundling these items at a reasonable cost could provide significant public value.	As noted above, suggestion added to Section 4.3 ('Review of benefits and claiming arrangements').
65	Clinical expert	The report promotes the conclusion that surgical guides and biomodels are not needed in simple dental implant surgery. I would agree that biomodels are of minimal benefit, but surgical guides are essential. When dental implants are placed in an outpatient setting, the positioning of the implant is repeatedly checked throughout the procedure with intra-oral radiographs. This is not possible in an operating theatre due to the unavailability of dental radiographs, as well as the increased theatre time required to do this. A surgical guide largely circumvents the need for intra-operative radiographs by facilitating accurate positioning of the dental implant. I use a surgical guide for every implant case.	Footnote added to instances where we suggest dental implants do not meet criterion 4: 'Excluding circumstances where dental implants are placed at the same time as a complex CMF procedure.'
66	Clinical expert	*Regarding clinical complexity of procedures* Most of the categories have been correctly classified. However, with the advent of virtual surgical planning and guides, as per my interview, we are also able to reconstruct and at the same time provide immediate implant based dental rehabilitation to restore the patient's missing dentition from their cancer resection. There is beyond doubt that the reduction in hospital admissions, multiple surgeries provides an overall reduction in treatment cost for the patient and operative complications.	As above, footnote added to instances where we suggest dental implants do not meet criterion 4: 'Excluding circumstances where dental implants are placed at the same time as a complex CMF procedure.'
67	Clinical expert	We recognise that an excessive number of models and guides are often provided to the surgeon. This is mainly driven by certain commercial providers. We would favour a process where the role of specific guide and biomodel needs to be detailed / defined, rather than a blunt instrument such as a number limit for all the complex CMF surgeries. The purpose of each guide and model required should be detailed by the surgeon and approved by an independent body (not the private health insurer)	Added to suggestions (Section 4.3) under 'Restriction of circumstances in which benefits are payable'. This comment also relates to the suggestion of guidelines (see 1st bullet point in Section 5). "

68	Clinical expert	*Regarding stakeholder suggestions: Review of costs:* Suggestions made above to improve the PL listing sounds sensible. • The improvement should be considered for patient, healthcare system and private health perspective and approved by an independent body (not the private health insurer). • Advocate and submit for MBS codes for use of surgical guides • The virtual surgical planning (VSP) process requires reimbursement via a MBS code, once VSP is MBS code item, it can bring the cost of surgical guides and biomodels down as the cost of VSP session is currently included in the price of the surgical guides and biomodels.	Suggestion of funding for VSP (and virtual biomodels) added to Section 4.3 under 'Review of benefits and claiming arrangements'.
69	Peak body	This section defines 'surgical guides' which include cutting guides, surgical splints, and plates. This definition is correct as it is broad, however in this section whilst 'cutting guides' are separately defined, 'surgical splints' are not defined separately. The failure to recognise 'surgical splints' as a separate (and cheaper type of surgical guide) which can be used for many cases (without biomodels and cutting guides) is relevant. 'Surgical splints' are used for many of the procedures in CMF, not for cutting the bone but to accurately reposition the bones in space before fixing the bone into its final position. Understanding the distinction and their role is important in making the final recommendations.	'Surgical splint' now defined in glossary to support recommendation to separate these from other surgical guides.
70	Peak body	*Regarding stakeholder suggestions: Review of costs:* Even in simple cases, 'virtual biomodels' may play an important role in identifying anatomical variations, avoiding placement of implants into important structures such as nerves, and improving accuracy and planning. However, in these cases a printed model may not be required. In these cases, a printed surgical splint (significantly cheaper) may suffice. This is an opportunity to reduce costs whilst maintaining the ability of the surgeon to use this important surgical tool to improve patient outcome.	As above, suggestion of funding for VSP (and virtual biomodels) added to Section 4.3 under 'Review of benefits and claiming arrangements'. Suggestion of separating out surgical splints already incorporated.
71	Peak body	Another key piece of literature that is not listed in the examination of the evidence using 3D printed technologies in surgery has been outlined in "Future of Surgery" report by RCS England and referenced on the RACS website (a copy has been attached).	This has been referenced and a quote included in the context of future trends, Section 1.3.

72	Peak body	*Regarding stakeholder suggestion: Providing guidance, including examples and images, of the surgical guides and biomodels listed and the circumstances under which they are considered eligible".* Please provide clarification regarding who will provide this "guidance". This should be clinician led and expert driven and subject to regular review, given the evolving nature of technology.	New heading ('Review of governance arrangements') and supporting text added to stakeholder suggestions (Section 4.3).
73	Peak body	*Closing remark:* The best practice approach is to have a system that is flexible and (expert) clinician led and produces guidelines which are regularly updated. Such an approach has so far not been adopted and should be implement first before advocating for clinically restrictive measures. Thus far, the current number of printed biomodels and guides provided to clinicians has been determined by the commercial companies themselves without surgeons' input.	Partially captured in governance and limits themes. Addition made in Section 5 (1st bullet) to capture recommendation for guidelines.
No action required			
74	Sponsor	We support the recommendation from AHA for greater engagement with surgeon users prior to removal of a product or limiting its use.	No action required – supportive of recommendations from section 5.
75	Peak body	*Responding to stakeholder suggestions: Placing limits on the benefits payable through the PL* Supported. This is the most urgent action to address consumer harm.	No action required – supportive of suggestion in section 5.
76	Clinical expert	*Regarding stakeholder suggestions: The costs and benefits of point-of-care manufacturing hubs be further explored.* We welcome the support and reimbursement pathway provided for the hospital point-of-care manufacturing. We would be keen to be involved in discussion along with other point-of-care manufacturing institutions.	No action required – supportive of suggestion in section 5.
77	Sponsor	*Responding to stakeholder recommendation: Addressing some of these issues in the context of concurrent work to reorganise or recategorise products currently listed on the PL* We endorse the Department's ongoing regrouping review with suggestions in our submission that surgical guides should be separated from splint guides to better align to costs and the complexity of implant type	No action – statement of agreement for section 5.

78	Sponsor	When considering the published evidence, studies that were analysed by this review show comparative or improved clinical and cost effectiveness for surgical guides and biomodels. For surgical guides and biomodels aided by virtual surgical planning (VSP) compared to conventional (freehand) surgery, improved outcomes for VSP included: reduced ischemia time, reduced operative time, length of stay and reduced ICU stay, increased surgical accuracy and precision and facial appearance and reduced cost. Three studies also found similar surgical accuracy.	No action required.
79	Clinical expert	*Regarding clinically complex categories listed in the report in section 4.3* We believe all categories / types of procedures have been covered for complex CMF procedures	No action required – supportive of section 4.3.
80	Clinical expert	*Regarding stakeholder suggestions: Review and re-categorisation of PL sub-categories and product groups* We agree with the suggestion to • Separate dental implant guides from CMF surgical guides • Separate out splint guides	No action required – supportive of suggestion in section 5.
81	Peak body	[We] agree that specifying appropriate MBS items for which surgical guides and biomodels are eligible for benefits is a viable solution to reducing utilisation outside the clinical indications of the primary prothesis, the intention of PL grouping structure and scope of PL eligibility.	No action required – statement of agreement.
82	Peak body	[We] support AHAs assessment that SGs are frequently used in complex CMF procedures with demonstrated clinical benefits. [We] supports AHAs statement that most stakeholders, including surgeons and peak clinical bodies consider SG&Bs are standard-of-care for complex CMF surgeries.	No action required – statements of agreement.
83	Peak body	[We] note that the broader evidence utilised to supplement the evidence in section 2.2 was largely comprised of dental implant studies. Their relevance to the broader category is questionable and should not be used to call into question the use of surgical guides and biomodels for craniomaxillofacial surgery, as they are intended to be used on the PL.	No action required – the report acknowledges the important clinical role of surgical guides and biomodels.
84	Peak body	[We] agree with AHAs review that as technology improves, indications expand, and more research continues to be performed as across surgical disciplines, the utilisation of SG&Bs will continue increase as surgeon adoption increases.	No action required – statement of agreement.
85	Peak body	[We] strongly supports AHAs statement that as part of their investigation surgeons directly highlighted that increased utilisation is driven by improved patient outcomes and inclusion of SG&Bs as a core part of surgical training. This is alignment with the above statement this this technology is now considered standard-of-care for complex CMF surgeries.	No action required – statement of agreement.

86	Peak body	[We] also support clarifying the role of surgical guides and biomodels as individual products and as elements of 'kits' or bundles currently listed on the PL. We would add that the issue of what items are including in kits or bundles and how they might be accessed individually when clinically necessary is not limited to a discussion of surgical guides and biomodels and needs to be considered more broadly in relation to other PL and PL-like items.	No action required – outside scope of report.
87	Peak body	[We] support the following proposal from the Draft Review to clarify the eligibility criteria by •Amending the PL criteria to include a meaning of essential in Criterion 4(b)and clarify the meaning of integral for the purposes of surgical guides and biomodels. •Providing guidance, including examples and images, of the surgical guides and biomodels listed and the circumstances under which they are considered eligible.(Page 82) As this is a technical and complex area [we] believe that the development of clear guidance is important and must be developed in full consultation with the medical profession.	No action required – statement of agreement. Addition already made in Section 5 (1st bullet) to capture recommendation for guidelines.
88	Peak body	[We] support reform of the Protheses List (PL) to improve clinical effectiveness and to deliver a more efficient pricing structure. We also believe that the key underlying principle for all reforms to the Prostheses List must be to improve clinical outcomes for patients. [We] recognise the need to address the full range of policy settings and levers supporting the use of prostheses items in the private health sector. [We] support streamlining the PL and modernising and improving its processes. We have supported revising the definition of PL and therefore items (that no longer meet the new definitions) being removed from the PL.	No action (about PL reforms in general and beyond scope of this review).
89	Peak body	[We] do not support inappropriate claiming or fraud. Compliance is something the [we] take very seriously, and we have a strong record of working with government to ensure that Medicare funding is directed to support patients.	No action required – out of scope.
90	Peak body	[We] agree with the statement in the Draft Review that: Use of surgical guides and biomodels is expected to continue and broaden as the technology improves and manufacturing costs reduce. Clinicians also suggested that increased use is driven by improved patient outcomes, and the inclusion of surgical guides and biomodels as a core part of surgical training.(Page 6)	No action – statement of agreement.

91	Peak body	[We] support the overarching outcomes of this review in that; - Surgical guides are frequently and appropriately used in complex CMF surgeries involving prosthetic implants. - Biomodels in comparison to surgical guides are seen as less useful, but still play an important role in clinical practice. - The available clinical evidence supports the use of SG&Bs across a range of contexts including CMF applications and frequently suggests that the use of 3D technologies, including SG&Bs produces results that are not inferior to 'conventional' techniques and may have additional benefits. As technology improves, indications expand, and more research continues to be performed as across surgical disciplines, the utilisation of SG&Bs will continue increase as surgeon adoption increases.	No action – statement of agreement.
92	Peak body	Given the above outcomes as stated by AHA within their review and in alignment with the questions being proposed by the Department, [we] believe this review has demonstrated that SG&Bs have an established role in clinical practise, an evidence base supporting their clinical effectiveness and adhere to the Prostheses List eligibility criteria.	No action required.
93	Peak body	In saying that, [we] agree with AHAs statement that clinical literature supports the use of SG&Bs across a range of contexts including oral and CMF applications, orthopaedics, cardiovascular surgery, and ENT surgery.	No action – statement of agreement.
94	Sponsor	We note the application of 3D models and guides in surgical training programs. The inclusion of a procedure into Surgical Society training programs occurs only for established technologies which are known to be beneficial to patients. This decision is driven by clinicians and confirms the clinical relevance and importance of ensuring the availability of this technology to private patients.	No action required – supportive of findings in TOR 1.
95	Sponsor	The report assesses the utilisation of surgical biomodels and guides, noting that there has been a significant increase in the utilization of guides and biomodels. We have seen these increases occur due to expansions in indications -surgeons are seeing value in greater surgical accuracy using these products, and patients are benefitting from greater accuracy and clinical and functional outcomes.	No action required – supportive of findings in TOR 1 and 3.
96	Sponsor	We recommend the inclusion of the patient voice in the stakeholder review.	No action required – Consumer Health Forum were approached to participate in the review however did not participate. This is referred to under 'other organisations', Appendix A.

97	Sponsor	*Responding to stakeholder recommendation: Placing limits on the benefits payable through the PL* Benefits can follow the current process within PL reform aligned to re-grouping, thus public sector pricing is a more consistent approach.	No action required – out of scope.
98	Sponsor	*Responding to stakeholder recommendation: Investigating areas where it is suggested that benefits are being claimed inappropriately (e.g. in the absence of a prosthesis, or where the procedure could be performed outside of a hospital or hospital-substitute setting)* [We] agree that for outlier cases, this should be upheld to prevent and avoid what PHI are currently advised by PHA to reject all claims for SGB use at present. PHI currently writing to private hospitals pre-empting that SGB do NOT meet a PL criterion as a result of the Department calling this post listing review is a breach of the current obligations noted in the PHI Act. We suggest there must be clarity on the definition of an outlier episode to avoid the current and distressing reimbursement rejections we see from PHI at present.	No action required – out of scope.
99	Sponsor	The offset across the full episode of care warrants acknowledgement. We endorse as AHA note, there are reductions in anaesthetic time, reductions in the total number of surgical interventions required with SGB use and a potential for shorter length of stay.	No action required – statement of agreement re: TOR 1.
100	Sponsor	We acknowledge and support AHA suggestions for the Department	No action required – statement of agreement for section 5.
101	Sponsor	We strongly challenge the inclusion of the views of Private Health Insurance representatives who are not clinicians and should not be in a position to comment on whether a product is necessary in a clinical setting, and are motivated to limit the funding of products on the PL.	No action required – all stakeholders nominated by the department have been provided equal opportunity to contribute to the review.
102	Sponsor	One of the intended purposes of the review was determine if surgical guides and biomodels meet the criteria for listing on the Prosthesis List. We acknowledge and agree with AHA's determination that surgical guides and biomodels meet the criteria for Prosthesis Listing.	This is not quite what the report says, but no action required.

103	Peak body	[We] largely support AHAs assessment on whether the listed SG&Bs meet the eligibility criteria for listing on the PL. In relation to the 5 eligibility criteria AHA demonstrated that; - Of the 32 products, 30 products are entered and current on the ARTG and the remaining 2 products are registered under transition arrangements, so this criterion is considered met. - All products are provided to a person as part of an episode of hospital treatment or hospital-substitute treatment, so this criterion is met. Medicare benefits were payable for all instances where benefits for the listed surgical guides and biomodels were paid, so this criterion is met.	No action required – statement of support.
104	Peak body	[We] also note that AHA established in their investigation and review of ToR 1, that surgeons and peak bodies directly highlighted that increased utilisation is driven by improved patient outcomes and inclusion of SG&Bs as a core part of surgical training. This is also alignment with the statement this this technology is now considered standard-of-care for complex CMF surgeries.	No action required – statement of agreement.
105	Clinical expert	In response to TOR 3: We do not have any further comments for current utilisation patterns of surgical guides and biomodels listed on the PL.	No action required.

106	Clinical expert	In response to TOR 3: For CMF cancer resection and reconstruction, below MBS item numbers, ICD classification and DRG are commonly used for the surgeries utilising surgical guides and biomodels. We have listed below for reference as they are very different to those used for orthognathic surgeries. MBS item numbers 30275: RADICAL EXCISION OF INTRAORAL TUMOUR INVOLVING RESECTION OF MANDIBLE AND LYMPH NODES OF NECK 45561: MICROVASCULAR ANASTOMOSIS 45564: Free transfer of tissue reconstructive surgery 45565: Free transfer of tissue reconstructive surgery 45845: OSSEO-INTEGRATION PROCEDURE DRG: A06A: Tracheostomy W Ventilation >=96hrs W Catastrophic CC A06B: Ventilation >=96hrs and OR Proc (W/O Tracheostomy or W/O Cat CC) D02A: Head and Neck Interventions, Major Complexity I02A: Microvascular Tissue Transfers or Skin Grafts, Excluding Hand, Major Complexity I02B: Microvascular Tissue Transfers or Skin Grafts, Excluding Hand, Intermediate Com	No action required. Note that, in TOR3, we only reported on the MBS item numbers for which data were given to us.
107	Sponsor	*Responding to stakeholder recommendation: Placing limits on the benefits payable through the PL* Agree that specifying the MBS items for which surgical guides and biomodels are eligible for benefits through the PL mechanism would ensure clarity and certainty to the treating surgeons, to which sponsors can oblige supply. Specifying an MBS items for which SGB are eligible aligns to the principle of listing on the PL. This is a viable solution to ensure utilisation reflects the clinical indications of the primary prothesis.	No action required – statement of agreement for section 5 in relation to linking MBS codes to product utilisation.
108	Sponsor	We endorse the body of published clinical evidence analysis and final summation.	No action required – statement of agreement re: TOR 2.
109	Sponsor	We acknowledge and agree that all relevant stakeholder feedback as detailed in AHA's review represents a balanced perspective of the role surgical guides, splint guides and biomodels have in current clinical practice.	No action required – statement of agreement re: TOR 1.

110	Peak body	The AHA Report demonstrates that based on available clinical evidence as well key insights from peak clinician bodies that surgical guides and biomodels are clinically effective and provide substantial benefit to patients in clinical practise. The Report additionally demonstrates that the majority, if not all, surgical guides and biomodels meet the Prostheses List criteria for listing.	This is not quite what the report says, but no action required.
111	Peak body	In alignment with available clinical evidence and the insights provided by clinicians with respect to procedure utilisation, [we] agree that specifying appropriate MBS items for which surgical guides and biomodels are eligible for benefits is a viable solution to reducing utilisation outside the clinical indications of the primary prothesis, the intention of PL grouping structure and scope of PL eligibility.	No action required – statement of agreement.
112	Sponsor	[We] acknowledge Australian Healthcare Associates (AHA) have comprehensively addressed the ToR as follows: 1.Analyse the role in clinical practice of surgical guides and biomodels currently listed on the PL, including future trends in clinical use. 2.Review the evidence base for the use of surgical guides and biomodels currently listed on the PL, with a focus on comparative clinical effectiveness and clinical benefits. 3.Consider the current utilisation of surgical guides and biomodels listed on the PL. 4.Based on the findings of ToR 1, 2 and 3, advise if surgical guides and biomodels meet the eligibility criteria for listing on the PL. Findings regarding eligibility may differ between products and clinical circumstances.	No action required – statement of agreement.
113	Sponsor	[We] support the key findings in the report. We also agree that the terms used in the PL guide to define the eligibility of surgical guides and biomodels (SGB) remain open to interpretation due to a lack of more specific definitions of the patient population, clinical intervention by surgery type and essential technology to achieve the intervention, clinical need and expected outcome derived	No action required – statement of agreement.
114	Sponsor	[redacted]	No action (context to their products).
115	Sponsor	[Did not provide formal feedback on the draft report. Resubmitted their original submission from October 2022]	No action.

Appendix A References from submissions

#	Respondent type	Reference	Inclusion/exclusion and reason
1	Surgeon	Patel A, Harrison P, Cheng A, Bray B, Bell RB. Fibular Reconstruction of the Maxilla and Mandible with Immediate Implant-Supported Prosthetic Rehabilitation: Jaw in a Day. Oral Maxillofac Surg Clin North Am. 2019 Aug;31(3):369-386. doi: 10.1016/j.coms.2019.03.002. Epub 2019 Jun 1. PMID: 31164268.	Excluded: Descriptive article
2	Surgeon	Tang NSJ, Ahmadi I, Ramakrishnan A. Virtual surgical planning in fibula free flap head and neck reconstruction: A systematic review and meta-analysis. J Plast Reconstr Aesthet Surg. 2019 Sep;72(9):1465-1477. doi: 10.1016/j.bjps.2019.06.013. Epub 2019 Jul 2. PMID: 31324403.	Included in review of synthesised literature
3	Surgeon	Barr ML, Haveles CS, Rezzadeh KS, Nolan IT, Castro R, Lee JC, Steinbacher D, Pfaff MJ. Virtual Surgical Planning for Mandibular Reconstruction With the Fibula Free Flap: A Systematic Review and Meta-analysis. Ann Plast Surg. 2020 Jan;84(1):117-122. doi: 10.1097/SAP.0000000000002006. PMID: 31633539.	Included in review of synthesised literature
4	Surgeon	Rodby KA, Turin S, Jacobs RJ, Cruz JF, Hassid VJ, Kolokythas A, Antony AK. Advances in oncologic head and neck reconstruction: systematic review and future considerations of virtual surgical planning and computer aided design/computer aided modeling. J Plast Reconstr Aesthet Surg. 2014 Sep;67(9):1171-85. doi: 10.1016/j.bjps.2014.04.038. Epub 2014 May 15. PMID: 24880575.	Excluded: outside of the 5 year cut-off to be included in the review of synthesised literature
5	Surgeon	Baan F, Liebregts J, Xi T, Shreurs R, de Konig M, Berge S and MaalT. (2016) A New 3D Tool for Assessing the Accuracy of Bimaxillary Surgery: The OrthoGnathicAnalyser. PLoS One 11(2):e0149625.	Excluded: no relevant comparator
6	Surgeon	Zinser MJ, Failer HF, Ritter L, Braumann B, Maegele M, Zoller JE. (2013). A Paradigm Shift in Orthognathic Surgery? A Comparison of Navigation, Computer-Aided Designed/Computer-Aided Manufactured Splints, and "Classic" Intermaxillary Splints to Surgical Transfer of Virtual Orthognathic Planning. Americal Association of Oral and Maxillofacial Surgeons. 2151.e1	Excluded: not product specific
7	Surgeon	Pucci R, Priore P, Manganiello L, Cassoni A, Valentini V. (2019) . Accuracy of Virtual Surgical Planning (VSP) in Orthognathic Surgery: Comparison Between CAD/CAM Fabricated Surgical Splint and CAD/CAM Cutting Guides with PSI. AAOMS. e4-e5.	Excluded: Not product specific

8	Surgeon	M. Koyachi, K. Sugahara, K. Odaka, S. Matsunaga, S. Abe, M. Sugimoto, A. Katakura: Accuracy of Le Fort I osteotomy with combined computer-aided design/computeraided manufacturing technology and mixed reality. Int. J. Oral Maxillofac. Surg. 2021; 50: 782–790.	Excluded: No relevant comparator and not product specific
9	Surgeon	Shih-Jan C, Wilde F, Neuhaus M, Schramm A, Gellrich N-C, Rana M. Accuracy of virtual surgical planning of orthognathic surgery with aid of CAD/CAM fabricated surgical splint — a novel 3D analyzing algorithm, Journal of Cranio-Maxillofacial Surgery (2017), doi: 10.1016/ j.jcms.2017.07.016	Excluded: No relevant comparator and not product specific
10	Surgeon	De Riu G, Meloni SM, Baj A, Corda A, Soma D, Tullio A. Computer-assisted orthognathic surgery for correction of facial asymmetry: results of a randomised controlled clinical trial. British Journal of Oral and Maxillofacial Surgery 52 (2014) 251–257	Excluded: Not product specific
11	Surgeon	Schneider D, Kammerer PW, Henning M, Schon G, Thiem DGE, Bschorer R (2018). Customized virtual surgical planning in bimaxillary orthognathic surgery: a prospective randomized trial. Clinical Oral Investigations.	Excluded: Not product specific
12	Surgeon	Jones JP, Amarista FJ, Jeske NA, Szalay D, Ellis III E, Comparison of the Accuracy of Maxillary Positioning with Interim Splints versus Patient Specific Guides and Plates in Executing a Virtual Bimaxillary Surgical Plan, Journal of Oral and Maxillofacial Surgery (2022), doi: https://doi.org/10.1016/j.joms.2022.01.006.	Excluded from SR and review of systemised literature as while ProPlan was used a different software used for virtual surgical planning this was not a product on the Prostheses List. This article was however, referenced in the report.
13	Surgeon	T.-G. Kwon, J.-W. Choi, H.-M. Kyung, H.-S. Park: Accuracy of maxillary repositioning in two-jaw surgery with conventional articulator model surgery versus virtual model surgery. Int. J. Oral Maxillofac. Surg. 2014; 43: 732–738.	Excluded: Not product specific
14	Surgeon	F. G. Ritto, A. R. M. Schmitt, T. Pimentel, J. V. Canellas, P. J. Medeiros: Comparison of the accuracy of maxillary position between conventional model surgery and virtual surgical planning. Int. J. Oral Maxillofac. Surg. 2018; 47: 160–166.	Excluded: Not product specific
15	Surgeon	E. Shaheen, Y. Sun, R. Jacobs, C. Politis: Three-dimensional printed final occlusal splint for orthognathic surgery: design and validation. Int. J. Oral Maxillofac. Surg. 2016;	Excluded: No relevant comparator, no clinical outcomes reported
16	Surgeon	Tonin RH, Filho LI, Yamashita AL, da Silva Ferraz FW et al. Accuracy of 3D virtual surgical planning for maxillary positioning and orientation in orthognathic surgery. Orthod Carniofac Res. 2020; 23:229-236.	Excluded: No relevant comparator and not product specific

17	Surgeon	Zizelmann C, Hammer B, Gellrich N-C, Schweska-Polly R, Rana M, Bucher P. An Evaluation of Face-Bow Transfer for the Planning of Orthognathic Surgery, J Oral Maxillofac Surg. 70:1944-1950.	Excluded: Published before 2013
18	Surgeon	Royal College of Surgeons of England 'Future of Surgery' report	Excluded from systematic review and review of synthesised literature but it is mentioned in the report under 1.3.
19	Surgeon	Kumar, S. Evidence in surgery - levels and significance. Indian Journal of Surgery 81, pp. 307-316	Excluded from systematic review and review of synthesised literature but included in the report for contextual information and discussion on limitations
20	Peak body	J. Harding, J. K. Hartsfield Jr, A. S. Mian, B. P. Allan, S. Naoum, R. J. H. Lee, M. S. Goonewardene: Accuracy of mandibular proximal segment position using virtual surgical planning and custom osteosynthesis plates. Int. J. Oral Maxillofac. Surg. 2022; 51: 219–225.	Excluded: no relevant comparator
21	Peak body	A. Wong, M. S. Goonewardene, B. P. Allan, A. S. Mian, A. Rea: Accuracy of maxillary repositioning surgery using CAD/CAM customized surgical guides and fixation plates. Int. J. Oral Maxillofac. Surg. 2021; 50: 494–500	Excluded: no relevant comparator
22	Peak body	Lee R, Goonewardene MS, Mian A, Allan B, Brock D, Trevenen M. (2018) Accuracy of orthognathic surgery using 3D computer-assisted surgical simulation. Aust Orthod J; 34: 17-26.	Excluded: no relevant comparator
23	Peak body	Yoo HJ, Hartsfield Jr JK, Mian AS, Allan BP, Naoum S, Lee RJH, Goonewardene MS. Accuracy of mandibular repositioning using a new technology: CAD/CAM customized surgical cutting guides and fixation plates. Am J Orthod Dentofacial Orthop. 2022 Dec 8;S0889-5406(22)00729-6. doi: 10.1016/j.ajodo.2021.12.021.	Excluded: no relevant comparator
24	Sponsor	Abdelhay N, Prasad S, Gibson MP. Failure rates associated with guided versus non-guided dental implant placement: a systematic review and meta-analysis. BDJ Open. 2021 Aug 18;7(1):31.	Already included in review of synthesised literature
25	Sponsor	Fang Zhang, Xue Gao, Zhang-Yan Ye, Dong-Qian Xu, Xi Ding. The clinical accuracy of the implant digital surgical guide: A meta-analysis. Am J Dent. 2020 Dec;33(6):296-304.	Full-text not available

26	Sponsor	Leonardo Amorfini, Marco Migliorati, Sara Drago, Armando Silvestrini-Biavati; Immediately Loaded Implants in Rehabilitation of the Maxilla: A Two-Year Randomized Clinical Trial of Guided Surgery versus Standard Procedure. Clin Implant Dent Relat Res. 2017 Apr;19(2):280-295.	Already excluded from systematic review as not product specific
27	Sponsor	Romandini M, Ruales-Carrera E, Sadilina S, Hämmerle CHF, Sanz M. Minimal invasiveness at dental implant placement: A systematic review with meta-analyses on flapless fully guided surgery. Periodontology 2000. 2022 Jul 30.	Already included in review of synthesised literature
28	Sponsor	Younes F, Eghbali A, De Bruyckere T, Cleymaet R, Cosyn J. A randomized controlled trial on the efficiency of free-handed, pilot-drill guided and fully guided implant surgery in partially edentulous patients. Clin Oral Implants Res. 2019 Feb;30(2):131-138.	Already excluded from systematic review as not product specific
29	Sponsor	Gargallo-Albiol J, Barootchi S, Marques-Guasch J, Wang HL. Fully Guided Versus Half-Guided and Freehand Implant Placement: Systematic Review and Meta-analysis. Int J Oral Maxillofac Implants. 2020 Nov/Dec;35(6):1159-1169	Already included in review of synthesised literature
30	Sponsor	Frizzera F, Calazans NNN, Pascoal CH, Martins ME, Mendonca G. Flapless Guided Implant Surgeries Compared with Conventional Surgeries Performed by Non-experienced Individuals: Randomized and Controlled Split-Mouth Clinical Trial. Int J Oral Maxillofac Implants. 2021 Jul-Aug; 36(4): 755-761.	Already excluded from systematic review as not product specific
31	Sponsor	Seruya M, Fisher M and Rodriguez ED (2013) 'Computer-assisted versus conventional free fibula flap technique for craniofacial reconstruction: An outcomes comparison', Plastic and Reconstructive Surgery, 132(5):1219–1228, doi:10.1097/PRS.0b013e3182a3c0b1	Already included in systematic review
32	Sponsor	Wang Y, Fan S, Zhang H, Lin Z, Ye J and Li J (2016) 'Virtual surgical planning in precise maxillary reconstruction with vascularized fibular graft after tumor ablation', Journal of Oral and Maxillofacial Surgery, 74(6):1255–1264, doi:10.1016/j.joms.2016.01.010	Already included in systematic review
33	Sponsor	Mazzola F, Smithers F, Cheng K, Mukherjee P, Low T, Sydney C, Palme C and Clark J (2019) 'Time and cost-analysis of virtual surgical planning for head and neck reconstruction: a matched pair analysis', Oral Oncology, 100(2020	Already included in systematic review
34	Sponsor	Resnick CM, Inverso G, Wrzosek M, Padwa BL, Kaban LB and Peacock ZS (2016) 'Is there a difference in cost between standard and virtual surgical planning for orthognathic surgery?', Journal of Oral and Maxillofacial Surgery, 74(9):1827–1833, doi:10.1016/j.joms.2016.03.035.	Already included in systematic review

35	Sponsor	Zweifel DF, Simon C, Hoarau R, Pasche P and Broome M (2015) 'Are virtual planning and guided surgery for head and neck reconstruction economically viable?', Journal of Oral and Maxillofacial Surgery, 73(1):170–175, doi:10.1016/j.joms.2014.07.038.	Already included in systematic review
36	Sponsor	Zhang WB, Yu Y, Wang Y, Mao C, Liu XJ, Guo C Bin, Yu GY and Peng X (2016) 'Improving the accuracy of mandibular reconstruction with vascularized iliac crest flap: role of computer-assisted techniques', Journal of Cranio-Maxillofacial Surgery, 44(11):1819–1827, doi:10.1016/j.jcms.2016.08.014.	Already included in systematic review
37	Sponsor	Weitz J, Bauer FJM, Hapfelmeier A, Rohleder NH, Wolff KD and Kesting MR (2016) 'Accuracy of mandibular reconstruction by three-dimensional guided vascularised fibular free flap after segmental mandibulectomy', BritishJournal of Oral and Maxillofacial Surgery, 54(5):506–510, doi:10.1016/j.bjoms.2016.01.029	Already included in systematic review
38	Sponsor	Johal M, Ma J, Parthasarathi K, Dunn M, Howes D, Wallace C, Palme C, Leinkram D, Cheng K and Clark J (2022) 'Institutional-based and commercial virtual surgical planning in maxillomandibular reconstruction -comparing the digital and postoperative scan', Journal of Plastic, Reconstructive & Aesthetic Surgery, 75:1399–1407.	Already included in systematic review
39	Sponsor	Rommel N, Kesting MR, Rohleder NH, Bauer FMJ, Wolff K-D and Weitz J (2017) 'Mandible reconstruction with free fibula flaps: outcome of a cost-effective individual planning concept compared with virtual surgical planning', Journal of Cranio-Maxillo-Facial Surgery, 25(2017):1246–1250	Already included in systematic review
40	Sponsor	De Maesschalck T, Courvoisier DS and Scolozzi P (2017) 'Computer-assisted versus traditional freehand technique in fibular free flap mandibular reconstruction: a morphological comparative study', European Archives of Oto-Rhino-Laryngology, 274(1):517–526, doi:10.1007/s00405-016-4246-4.	Already included in systematic review

Appendix B Descriptions of key terms and clinical examples

The following provides descriptions of key terms and clinical examples provided as an Appendix in a submission.

Virtual Surgical Planning

In order to discuss the suitability of surgical guides and models for listing on the PL, it is important to note that they are, along with patient matched implants, products designed in order to translate a virtual surgical plan to the surgical situation. Virtual surgical planning (VSP) for the range of craniofacial/ maxillofacial surgeries and head and neck reconstruction is the broadly accepted standard of care. In addition to the clinical reasons, VSP is an important tool to communicate sufficient information to the patient about the procedure, enabling them to provide informed consent for their medical treatment. A detailed case report with images of the surgical plan and the patient matched products are a crucial tool for the surgeon to communicate the plan to the patient and obtain informed consent. This is particularly critical for orthognathic surgery where most patients are under 18 years of age.

Surgical guides, anatomical biomodels and patient matched implants (PMI) are designed specific to a patient's anatomy utilizing CT scan data and a variety of software that an engineer segments to create a 3D diagnostic visualization of the area of interest. All these products are single use and specific to the patient they have been designed for.

Surgical Guides

Surgical guides are patient matched devices designed to osteotomise and guide the positioning of bone segments and/or a patient matched implant in accordance with a virtual surgical plan. They are temporarily implanted into the patient either by fixation screws or secured to MMF screws or orthodontic brackets with wire, depending on the specific type of guide.

After the osteotomies and bone positioning are virtually planned, 1 or more surgical guides are required to guide the simulated bone movements intraoperatively. This is achieved by incorporating drilling sleeves/tubes into the guide that correlate exactly to the planned screw hole position of the associated PMI. Positioning indicators which correlate to anatomical landmarks may also be used to accurately position the guide. The associated PMI cannot be implanted as per the simulated planning without the use of the patient matched surgical guide. The minimum quantity of guides required to achieve the surgical plan depends on the clinical indication. In the case of mandible resection with fibula free flap, the reconstructed fibula/plate construct is typically transferred as one piece to the patient's head, accurately matching the defect created by the mandible resection and aligning with predrilled screw holes.

Surgical Guide Splints

Orthognathic surgical splints are surgical guides used in single or double jaw surgery to guide the mobile jaw segments into their virtually planned dental occlusion. These may be used to implant a PMI, or they can be used to implant standard plates. There is clinical conjecture around "splintless" surgery and it is not currently standard clinical practice. It should be noted that splintless surgery must be performed with a PMI and surgical guide in order to pre-drill the implant holes to ensure accurate positioning of the implant and bone segments. Even in these cases, it is standard practice to verify the correct position with the

repositioning splint. An unintended economic consequence if splints are not reimbursed is the increased uptake by surgeons of PMIs in order to offer virtual surgical planning and avoid out of pocket costs. Again, it should be noted that a surgical guide would be essential in this case. There are many surgeons still performing orthognathic surgery with standard plates so there is a large potential for the increased uptake of PMIs to offset the cost savings of not reimbursing splints.

Anatomical Biomodel

Anatomical Biomodels are a single use patient matched device designed and produced from the patient's CT scan. Once the surgery is simulated virtually, including osteotomies and bone repositioning, one or more biomodels will be produced to replicate various stages of the surgery. These enable the surgeon to visualise and manage surgical approaches and may offer a fast, cost-effective solution where a standard plate is preferred over a PMI e.g., delayed presentation of primary orbital trauma and urgent reconstruction required.

There is a distinction between anatomical biomodels which are simple replicas of the patient's anatomy based on the CT scan and modelled reconstructions of the surgical plan which require design prior to production.

Clinical examples:

Orbital/midfacial trauma – A reconstructed orbit/midface is created based on the mirror image of the contralateral side. This is used to pre-bend a plate either prior to or at the time of surgery. The shape of the model bent plate is used to aid the bone repositioning to achieve facial symmetry according to the virtual plan. In the case of primary orbital trauma, it is often necessary to use a standard plate rather than a PMI due to delayed presentation and insufficient time to design and produce a PMI to meet the standard of care timeline.

Midface/Mandible oncology reconstruction with free flap – If urgent surgery is required and there is insufficient time to produce a PMI due to malignancy, VSP is still performed and select verification and reconstruction models are provided that enable the surgeon to bend a standard reconstruction plate according to the plan and verify surgical steps such as resection margins. There are also rare instances where the cancer has advanced so rapidly that the surgical plan must be revised intraoperatively. The surgeon needs models to visualise and mark the new resection margins and bend a standard plate if the PMI cannot be used.

From: s22
To: s22
Subject: Conditions for billing codes for surgical guides and biomodels [SEC=OFFICIAL:Sensitive]
Date: Tuesday, 19 September 2023 2:54:37 PM
Attachments: image003.png
MBS items for cmf with implants.docx

Hi s22

After our meeting yesterday I have done some research on MBS items for craniomaxillofacial services that might involve and implant, to inform advice on conditions.

s 47C

s 22

s 22
Assistant Director – 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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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

MBS ITEMS FOR CMF SURGERY

New 45592	Orbital cavity, reconstruction of wall and floor with bone graft, cartilage graft or foreign implant, other than a service associated with a service to which item 45594 applies on the same side (H) (Anaes.) (Assist.) **Fee:** $932.25 **Benefit:** 75% = $699.20
New 45874	Temporomandibular joint, including condylar head and glenoid fossa, total alloplastic replacement (H) (Anaes.) (Assist.) Fee: $1,443.35 Benefit: 75% = $1082.55
New 46150	Mandible or maxilla, procedure for advancement, retrusion or alteration of tilt, by osteotomy in standard planes, including fixation by any means (including application of distractors if used)—one service per patient on the same occasion (H) (Anaes.) (Assist.) (See para TN.8.107, CN.0.11, TN.8.269 of explanatory notes to this Category) Fee: $1,456.40 Benefit: 75% = $1092.30
New 46151	Mandible and maxilla (bimaxillary), procedure for advancement, retrusion or alteration of tilt, or combination of these, by osteotomies in standard planes, including fixation by any means (including application of distractors if used)—conjoint surgery, principal specialist surgeon, one service per patient on the same occasion (H) (Anaes.) (Assist.) (See para TN.8.107, CN.0.11, TN.8.269 of explanatory notes to this Category) Fee: $1,588.00 Benefit: 75% = $1191.00
New 46152	Mandible and maxilla (bimaxillary), procedure for advancement, retrusion or alteration of tilt, or combination of these, by osteotomies in standard planes, including fixation by any means (including application of distractors if used)—conjoint surgery, conjoint specialist surgeon, one service per patient on the same occasion (H) (Anaes.) (Assist.) (See para TN.8.107, CN.0.11, TN.8.269 of explanatory notes to this Category) Fee: $1,191.00 Benefit: 75% = $893.25
New 46153	Mandible and maxilla (bimaxillary), procedure for advancement, retrusion or alteration of tilt, or combination of these, by osteotomies in standard planes, including fixation by any means (including application of distractors if used)—single surgeon, one service per patient on the same occasion (H) (Anaes.) (Assist.) (See para TN.8.107, CN.0.11, TN.8.269 of explanatory notes to this Category) Fee: $1,984.90 Benefit: 75% = $1488.70
New 46154	Maxilla, procedure for reshaping arch of, by complex segmental osteotomies, including fixation by any means (including application of distractors if used), one service per patient on the same occasion (H) (Anaes.) (Assist.) (See para TN.8.107, CN.0.11 of explanatory notes to this Category) Fee: $1,662.20 Benefit: 75% = $1246.65
New 46155	Mandible, procedure for reshaping arch of, by complex segmental osteotomies, including genioplasty (if performed) and fixation by any means (including application of distractors if used), one service per patient on the same occasion (H) (Anaes.) (Assist.) (See para TN.8.107, CN.0.11 of explanatory notes to this Category)

MBS ITEMS FOR CMF SURGERY

	Fee: $1,662.20 Benefit: 75% = $1246.65
New 46156	Mandible and maxilla (bimaxillary), procedure for any combination of arch reshaping, advancement, retrusion or tilting of, involving complex segmental osteotomies, with or without standard osteotomies, including genioplasty (if performed) and fixation by any means (including application of distractors if used)—conjoint surgery, principal specialist surgeon, one service per patient on the same occasion (H) (Anaes.) (Assist.) (See para TN.8.107, CN.0.11 of explanatory notes to this Category) Fee: $1,897.60 Benefit: 75% = $1423.20
New 46157	Mandible and maxilla (bimaxillary), procedure for any combination of arch reshaping, advancement, retrusion or tilting of, involving complex segmental osteotomies, with or without standard osteotomies, including genioplasty (if performed) and fixation by any means (including application of distractors if used)—conjoint surgery, conjoint specialist surgeon, one service per patient on the same occasion (H) (Anaes.) (Assist.) (See para TN.8.107, CN.0.11 of explanatory notes to this Category) Fee: $1,423.20 Benefit: 75% = $1067.40
New 46158	Mandible and maxilla (bimaxillary), procedure for any combination of arch reshaping, advancement, retrusion or tilting of, involving complex segmental osteotomies, with or without standard osteotomies, including genioplasty (if performed) and fixation by any means (including application of distractors if used)—single surgeon, one service per patient on the same occasion (H) (Anaes.) (Assist.) (See para TN.8.107, CN.0.11 of explanatory notes to this Category) Fee: $2,371.95 Benefit: 75% = $1779.00
Fee 45051	Contour reconstruction by open repair of contour defects, due to deformity, if: (a) contour reconstructive surgery is indicated because the deformity is secondary to congenital absence of tissue or has arisen from trauma (other than trauma from previous cosmetic surgery); and (b) insertion of a non-biological implant is required, other than one or more of the following: (i) insertion of a non-biological implant that is a component of another service specified in Group T8; (ii) injection of liquid or semisolid material; (iii) an oral and maxillofacial implant service to which item 52321 applies; (iv) a service to insert mesh; and (c) photographic and/or diagnostic imaging evidence demonstrating the clinical need for this service is documented in the patient notes (Anaes.) (Assist.) Fee: $518.90 Benefit: 75% = $389.20
Fee 52105	PLATE, 1 or more of, and associated screw and wire which were inserted for internal fixation purposes into maxilla or mandible or zygoma, removal of, requiring anaesthesia, incision, dissection and suturing, per bone, not being a service associated with a service to which item 52099 or 52102 applies (Anaes.) (Assist.) Fee: $288.70 Benefit: 75% = $216.55 85% = $245.40

MBS ITEMS FOR CMF SURGERY

Fee 52106	ARCH BARS, 1 or more, which were inserted for dental fixation purposes to the maxilla or mandible, removal of, requiring general anaesthesia where undertaken in the operating theatre of a hospital (Anaes.) Fee: $119.25 Benefit: 75% = $89.45
Fee 52122	MANDIBLE, hemi-mandibular reconstruction of, OR MAXILLA, reconstruction of, with BONE GRAFT, PLATE, TRAY OR ALLOPLAST, not being a service associated with a service to which item 52123 applies (Anaes.) (Assist.) Fee: $906.10 Benefit: 75% = $679.60 85% = $812.90
Fee 52345	MANDIBLE or MAXILLA, unilateral osteotomy or osteectomy of, including transposition of nerves and vessels and bone grafts taken from the same site and stabilisation with fixation by wires, screws, plates or pins, or any combination (Anaes.) (Assist.) (See para ON.4.8 of explanatory notes to this Category) Fee: $1,194.15 Benefit: 75% = $895.65
Fee 52351	MANDIBLE or MAXILLA, bilateral osteotomy of osteectomy of, including transposition of nerves and vessels and bone grafts taken from the same site and stabilisation with fixation by wires, screws, plates or pins, or any combination (Anaes.) (Assist.) (See para ON.4.8 of explanatory notes to this Category) Fee: $1,515.45 Benefit: 75% = $1136.60
Fee 52357	MANDIBLE or MAXILLA, osteotomies or osteectomies of, involving 3 or more such procedures on the 1 jaw, including transposition of nerves and vessels and bone grafts taken from the same site and stabilisation with fixation by wires, screws, plates or pins, or any combination (Anaes.) (Assist.) (See para ON.4.8 of explanatory notes to this Category) Fee: $1,729.55 Benefit: 75% = $1297.20
Fee 52363	MANDIBLE and MAXILLA, osteotomies or osteectomies of, involving 2 such procedures of each jaw, including transposition of nerves and vessels and bone grafts taken from the same site and stabilisation with fixation by wires, screws, plates or pins, or any combination (Anaes.) (Assist.) (See para ON.4.8 of explanatory notes to this Category) Fee: $1,984.90 Benefit: 75% = $1488.70
Fee 52375	MANDIBLE and MAXILLA, complex bilateral osteotomies or osteectomies of, involving 3 or more such procedures of each jaw, including genioplasty when performed and transposition of nerves and vessels and bone grafts taken from the same site and stabilisation with fixation by wires, screws, plates or pins, or any combination (H) (Anaes.) (Assist.) (See para ON.4.8 of explanatory notes to this Category) Fee: $2,371.95 Benefit: 75% = $1779.00
Fee 52382	MIDFACIAL OSTEOTOMIES - Le Fort II, Modified Le Fort III (Nasomalar), Modified Le Fort III (Malar-Maxillary), Le Fort III involving 3 or more osteotomies of the midface including transposition of nerves and vessels and bone grafts taken from the same site and stabilisation with fixation by wires, screws, plates or pins, or any combination (Anaes.) (Assist.) Fee: $2,860.35 Benefit: 75% = $2145.30 85% = $2767.15

MBS ITEMS FOR CMF SURGERY

Fee 52630	OSSEO-INTEGRATION PROCEDURE - in the practice of oral and maxillofacial surgery, fixation of transcutaneous abutment (Anaes.) Fee: $204.30 Benefit: 75% = $153.25 85% = $173.70
Fee 52633	OSSEO-INTEGRATION PROCEDURE - intra-oral implantation of titanium fixture to facilitate restoration of the dentition following resection of part of the maxilla or mandible for benign or malignant tumours (Anaes.) Fee: $551.90 Benefit: 75% = $413.95 85% = $469.15
Fee 52636	OSSEO-INTEGRATION PROCEDURE - fixation of transmucosal abutment to fixtures placed following resection of part of the maxilla or mandible for benign or malignant tumours (Anaes.) Fee: $204.30 Benefit: 75% = $153.25 85% = $173.70

s22

From: s22
Sent: Thursday, 1 June 2023 4:13 PM
To: s22
Cc: s47E(d) ; s22 ; s22 ; s22
Subject: FOR ACTION: POST LISTING REVIEW - SURGICAL GUIDES AND BIOMODELS [SEC=OFFICIAL]

s22

Further to s22 update in TLs and your previous advice on this matter, we need to obtain details of the catalogue numbers for the billing codes of the surgical guides and biomodels that were the subject of the post listing review. There were 32 billing codes on the PL as at the time of the research was undertaken by AHA, under the following specific groupings:

- 07.02.02.04 Cranium – surgical guides
- 07.02.05.07 Mandible, Maxilla and Temporomandibular Joint (TMJ) – surgical guides
- 07.02.09 Anatomical biomodels.

It is my understanding that we need to review the specific catalogue numbers and the relative products that this cover to ensure they are all surgical guides or biomodels and that there are no 'splints' included inadvertently.

Grateful if you could please arrange provision of the data for these 32 billing codes that will enable us to undertake this verification work.

Regards

s22
Director, Prostheses List Reform Taskforce

Technology Assessment & Access Division | Health Resourcing Group
Australian Government Department of Health
T: s22 | E: s22 @health.gov.au
M: s22
Location: Sirius Building s22
GPO Box 9848, Canberra ACT 2601, Australia

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.

Celebrating 100 YEARS OF HEALTH 1921 - 2021
Building a stronger, healthier country
Yesterday today and tomorrow

s22

From: s22
Sent: Thursday, 15 June 2023 10:01 AM
To: s22 ; s22
Cc: FLYNN, Elizabeth
Subject: Surgical guides and biomodels review draft report, key documents [SEC=OFFICIAL]
Attachments: PL review - surgical guides and biomodels - draft report.docx; Meeting 30 May 2023 with s22 docx; Meeting 22 May with s22 - Final.docx; Meeting 02 June 2023 with s22 final.docx

Hi s22 and s22
Please find attached the draft report for the Department's review of surgical guides and biomodels, incorporating the AHA review and the Department's own work, including the recent consultation phase. Comments and feedback welcome. If someone gets a chance, we could update the utilisation data to include 2021-22 FY.
I've also included records of the discussions that occurred as part of the recent consultation phase post the AHA report.
Can you please file in TRIM and send me the links – I'd do this myself, but keen not to meddle with our existing processes.
I'll plan to continue to progress this report on my return on 24 July 2023.
Best Regards
s22

s22

Medical Adviser

Technology Assessment and Access Division
Health Resourcing Group
Australian Government Department of Health
T: s22 | E: s22 @health.gov.au
Location: s22 595 Collins Street, Melbourne
GPO Box 9848 MDP 122, Melbourne VIC 3001, Australia

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

Australian Government
Department of Health

Celebrating 100 YEARS OF HEALTH 1921-2021

Meeting with s47F

Tues 30 May 5.30-6.45pm

Attendees

s47F

s22 – Medical Officer, Department of Health and Aged Care

Background

Following multiple meetings alongside the AHA review, an update was provided regarding the consultation with orthopaedics colleagues, and the Department's progress on the review, including PLAC update, Options paper, consideration of AHA report.

Discussion

Supports SGB final report including recommendations.

Would like to work with the Department on implementation as required.

There is good support at ANZAOMS for developing a position statement/guidelines regarding appropriate use of SGB. This is despite reservations amongst many surgeons around any unintended clinical consequences of any restrictions. Hence the position statement/guidelines might be expected to contain multiple provisos that highlight deficiencies in the current system that need to be addressed before it can be implemented (ie use of splints in simple jaw surgery).

For instance, the prostheses list currently provides a vehicle to obtain splints, which are necessary for surgery. They can be printed from virtual surgical planning software that forms part of biomodels. They can also be classified and billed as cutting guides in some instances.

If splints are no longer available through these avenues (ie if SGBs are not funded for simple jaw surgery), then there is a lack of alternative approaches. Historically, the labs used to make SGBs, but not possible to go back to this because this now not allowed by TGA. Can't use new technology, can't use old technology.

(Authors Note: after some exploration of this point, it appears that TGA reforms for surgical guides and biomodels have meant that these previous custom made medical devices are now patient matched medical devices, raising regulatory barriers).

Suggestion: Perhaps TGA could fast track approvals for MDPSs or exemption for splints

Consequently, in Europe, surgeons print their own splints and other devices. In Australia, unable to print own devices, means they have to be purchased from industry. There should be a discussion with TGA regarding this impact (Authors Note: re this reforms to personalised medical devices).

Noted that in many instances currently, private hospitals ask surgeons what (SGBs) they need prior to ordering. Suggested this as an approach to guard against companies supplying excessive amounts of devices, beyond that requested by surgeon.

Process re guidelines/position statement:

- PB to take to ANZAOMS council
- PB to develop draft in next 2-4 weeks to form basis for initial discussion with council
- Timeframe - draft available for wider consultation 2nd half of year

Meeting with s47F – 22 May 2023

Attendees

s47F – Spinal Surgeon and member of PLAC
s22 – Medical Officer, Department of Health and Aged Care
s22 – Post-market review, Department of Health and Aged Care

Background

In September 2022, the Department of Health and Aged Care (the department) commissioned Australian Healthcare Associates (AHA) to undertake a review of surgical guides and biomodels currently listed on the PL.

This review was undertaken to inform the department whether the listed surgical guides and biomodels are eligible for PL listing, and if a further cost-effectiveness review is required. This review considers the role of surgical guides and biomodels in clinical practice, utilisation patterns, and the evidence for their clinical benefits and clinical effectiveness, predominantly within craniomaxillofacial (CMF) and oral surgery.

Following the completion of the report, the Department noted the use of surgical guides and biomodels is growing in specialties other than CMF, notably in orthopaedics, and is seeking clarification on the following points.

- Whether surgical guides and biomodels are currently considered essential in any area of orthopaedics (and if so, under what circumstances) and/or spinal surgery, and
- How biomodels are used in orthopaedics/spinal surgery.

Meeting Minutes

s22 provided background information on the Review of Surgical Guides and Biomodels, and the reasons for the consultation process the Department is undertaking to seek further information.

s47F noted that his experience is as a spinal surgeon, and he was happy to provide input from that point of view. s47F noted that whether or not a product is considered 'essential' would differ from surgeon to surgeon. For example, a younger surgeon may consider a product essential as they have been trained to use them, while an older surgeon may have experience performing surgery without them and therefore consider them to be not essential. He noted there has been an increasing trend of the use of computer biomodelling by younger surgeons (rather than physical biomodels). This cost was initially born by the companies, but he noted these companies are facing more competition and may have less of a buffer to absorb these costs. He also noted a future trend in spinal surgery is the increasing use of robotics, with computer planning used to direct movements. He noted these new developments may make physical biomodels obsolete.

He also noted that surgical guides and biomodels may be considered essential in more complex surgeries but not in simple surgeries (as suggested by the AHA report) but noted that what is 'complex' and what is 'simple' is also subjective and interpretations may differ from surgeon to surgeon.

Overall, s47F view is that biomodels are not essential. However, he also noted the larger issue is that a biomodel is not implanted in the body but rather a tool used by a surgeon, therefore not appropriate for funding on the prostheses list. He considers the use of biomodels (or computer

generated biomodels) to be part of peri-operative planning. Therefore the cost should form part of the MBS rebate or hospital fee.

Supports including SGB in the PL but restricting it only to "complex" CMF Surgery.

Meeting with s47F – 2 June 2023

Attendees

s47F – Orthopaedic Surgeon and s47F

s22 – Medical Officer, Department of Health and Aged Care

s22 – Post-market review, Department of Health and Aged Care

Background

In May 2021, PLAC recommended that the Department of Health and Aged Care (the Department) do a post listing review of surgical guides and biomodels listed on the Prosthesis List (PL). Australian Healthcare Associates (AHA) was engaged to undertake a review and provide a report as part of the Department's review.

This AHA review report considers the role of surgical guides and biomodels predominantly within the craniomaxillofacial (CMF) area, since this is the area in the PL in which they are listed, and where most of the evidence is available. Less consideration was given to their use in Orthopaedics, though this is noted to be the main area of PL billing activity outside of CMF.

Noting the use of surgical guides and biomodels is growing in specialties other than CMF, notably in orthopaedics, and the Department sought clarification on the following points.

- Whether surgical guides and biomodels are currently considered essential in any area of orthopaedics (and if so, under what circumstances), and
- How biomodels are used in orthopaedics.

Meeting Minutes

- s22 provided background information on the PL reforms and Review of Surgical Guides and Biomodels, and the reasons for the consultation process the Department is undertaking to seek further information. He also defined biomodels as virtual or printed anatomical models.
- s47F noted that in his experience as an orthopaedic surgeon, he was happy to provide input about the essentiality of Biomodels and gave an example of the use of biomodels in shoulder surgery to ensure that the prosthesis goes in the best anatomical place. s47F noted that having a guide for standard joint joint replacement is not essential as a guide comes in the pack. Custom made guides are necessary for difficult primary and revision joint replacements.
- In answer to whether these products are considered 'essential', he stated that they are in some circumstances. Most notably, they are essential in certain types of complex surgery. Complex surgery is defined as procedures that involve difficult anatomy, revision surgery, and anatomical reconstruction. In these instances the Biomodels and the guides offer advantages. He noted that 3D models (part of biomodels) are part of a complex surgery plan. Surgical guides and biomodels are not essential for routine primary joint replacements and simple orthopaedic procedures.
- This technology is in its infancy and has not yet been proven to be better.
- He suggested the implementation of a form to be filled by surgeons outlining justification of use of a surgical guide or biomodel use prior to the surgery as a means of managing their use.
- Overall, s47F view is to list them but not across the broad range of applications. s47F would consider providing a position statement on SGB, as they have done for other areas -=

such as one for robot use in surgery, navigation and new technology. This would likely require input from across the various specialist groups within orthopaedics.

s22

From: s22
Sent: Wednesday, 18 October 2023 3:15 PM
To: s22
Cc: s22
Subject: MDHTP Rules - 1 November 2023 [SEC=OFFICIAL:Sensitive]
Attachments: Minute to AS - MDHTP Rules (No 2) 2023.DOCX; Private Health Insurance (Medical Devices and Human Tissue Products) Rules (No. 2) 2023.DOCX; Private Health Insurance (Medical Devices and Human Tissue Products) Rules (No. 2) 2023 - Explanatory Statement.DOCX; Schedule - Private Health Insurance (Medical Devices and Human Tissue Products) Rules (No.2) 2023.DOCX; PHI XX 23 Private Health Insurance (Medical Devices and Human Tissue Products) Rules (No. 2) 2023.DOCX

Importance: High

Dear s22

Please see attached documents for the November 2023 MDHTP Rules for your consideration, clearance, and signature.

The document have also been printed and TRIM references are below for your reference and consideration.

Please let me know if you have any questions.

D23-3496693 Minute to AS - MDHTP Rules (No 2) 2023 – for approval and signature
D23-3345401 Private Health Insurance (Medical Devices and Human Tissue Products) Rules (No. 2) 2023 - for approval and signature and date required
D23-3767970 Schedule - Private Health Insurance (Medical Devices and Human Tissue Products) Rules (No.2) 2023 – for review
D23-3347249 Private Health Insurance (Medical Devices and Human Tissue Products) Rules (No. 2) 2023 - Explanatory Statement - for review and approval
D23-3494129 PHI XX/23 Private Health Insurance (Medical Devices and Human Tissue Products) Rules (No. 2) 2023 - for review and approval

Thank you

s 22
s22
Director, Prostheses List Administration

Prostheses List Reform Taskforce | Technology Assessment and Access Division | Health Resourcing Group
Australian Government Department of Health and Aged Care
T: s22 | E: s22 @health.gov.au
Location Sirius Building s22

To: s22, Acting Assistant Secretary
Prostheses List Reform Taskforce
Technology Assessment and Access Division

PRIVATE HEALTH INSURANCE (MEDICAL DEVICES AND HUMAN TISSUE PRODUCTS) RULES – 1 NOVEMBER 2023

Purpose

To seek your decision to:

1. **SIGN** the *Private Health Insurance (Medical Devices and Human Tissue Products) Rules (No. 2) 2023* at Attachment A.
2. **APPROVE** the Explanatory Memorandum and the Statement of Compatibility with Human Rights at Attachment B.
3. **APPROVE** the Private Health Insurance (PHI) Circular at Attachment C.

Issues

The *Private Health Insurance Act 2007* (the Act) is the primary legislation regulating private health insurance, including the Prescribed List arrangements.

Section 333-20 (item 4) allows the Minister to make, by legislative instrument, *Private Health Insurance (Medical Device and Human Tissue Products) Rules* (the MDHTP Rules) for the purposes of Part 3-3 of the Act[1]. The MDHTP Rules set out the requirements in relation to the provision of benefits for medical devices and human tissue products. Schedule 1 to the MDHTP Rules is known as the Prescribed List of Medical Devices and Human Tissue Products (also known as the Prescribed List) (PL).

Under section 333-1 of the Act, the Minister may delegate their functions or powers under the Act. These powers and functions under the Act have been delegated to SES Band 2 and SES Band 1 in the Health Resourcing Group (refer to the Instrument of Delegation at TRIM D23-3128533).

Section 72-10 of the Act (Minimum benefits for medical devices and human tissue products) provides that the MDHTP Rules must only list a kind of medical device or human tissue product, if an application has been made under subsection (2) in relation to that kind of medical device or human tissue product and the Minister has granted the application.

On 17 October 2023, you signed the Minute seeking your decision to grant or not to grant new applications for medical devices and human tissue products to be listed on the Prescribed List (PL); and approve or not to approve changes (amendments and expansions) to existing PL billing codes (refer to *Granting minute* at TRIM D23-3764583).

Following granting of the new applications you, as the Minister's delegate, must list kinds of medical devices and human tissue products and set out the minimum benefits for those items by making or varying the MDHTP Rules. Signing the *Private Health Insurance (Medical Devices and Human Tissue Products) Rules (No. 2) 2023* (refer Attachment A / TRIM D23-3345401) will give effect to your decisions to grant the new PL applications and approve the changes to the existing PL billing codes.

A sponsor can also apply to *transfer their billing code to another sponsor*, or to *delete an existing billing code*. Signing the MDHTP Rules will also give effect to these changes.

Further, the MDHTP Rules may set out conditions that must be satisfied in relation to provision of a medical device or human tissue product of a kind listed in the MDHTP Rules or give effect to the removal of such conditions.

[1] Part 3-3 Requirement for complying health insurance products

The details of the changes effected in the *Private Health Insurance (Medical Devices and Human Tissue Products) Rules (No. 2) 2023* are below.

Changes to take effect on 1 November 2023	Part A	Part B	Part C	Part D
New billing codes following new applications *(Granting minute)*	207**	11	11**	0
New PL billing codes following expansion applications *(Granting minute)*	5 (2 applications)	0	0	0
New PL billing codes following transfer of sponsors	35	0	0	0
Total new billing codes	**247**	**11**	**11**	**0**
Removal of billing codes following deletion applications	4	14	0	0
Removal of billing codes after transfer of sponsors	34	0	0	0
Removal of billing codes after expansion applications	2	0	0	0
Total removed billing codes	**40**	**14**	**0**	**0**
Billing codes with changed details following amendment applications *(Granting minute)**	343	30	1	2
Total amended billing codes in the MDHTP Rules	**153**	**30**	**1**	**2*** **

* There is a difference in numbers of amendment applications between the Granting Minute and the Explanatory Statement to the Rules. The Schedule of the MDHTP Rules includes the following information: PL billing code; sponsor's name; description and size; category, sub-category, group, subgroup (if applicable) and suffix (if applicable); benefit; and condition (if any is placed on the PL code). Sponsors submit applications via the web-based Prostheses List Management System (PLMS) that requests sponsors also to provide ARTG entry and catalogue numbers relevant to the product listed on the Prescribed List. Information on ARTG entries is provided in the full version of the Prescribed List published on the Department's website but neither ARTG nor catalogue numbers appear in the legislative document. Respectively, amendment applications that only request changes to ARTG entries or catalogue numbers are not counted towards the changes to the billing codes effected by the Prostheses Rules amendments.
Some amendment applications were also created in PLMS by the Department to action the recommendations about placing conditions on the billing codes.
** The number of new applications in Granting Minute is 208 applications in Part A and 10 applications in Part C. This is different from this Minute because 1 application for Part C device was by mistake counted for Part A. This does not however impact in any way for the granting decision, as the granting decision was made for applications in all PL Parts.
*** The number of amendment applications in Granting Minute is 345 applications in Part A and 0 applications in Part D. This is different from this Minute because 2 applications for Part D billing codes was by mistake counted for Part A. This does not however impact in any way for the approval decision, as the approval decision was made for applications in all PL Parts.

Other changes

In addition to changes resulting from completion of the PL applications (above), the MDHTAC Rules have changes related to the Prostheses List reforms and the PL post-listing reviews [refer section Other Business and Attachment A in the Granting Minute].

One of the PL reforms' measure is to reduce the gap between the prices payable in public hospital and the PL benefits for the devices listed on the PL. Accordingly, the benefits for the general use items listed in the PL Part D have been reduced to the weighted public price payable for the same devices, as estimated by the Independent Health and Aged Care Pricing Authority (IHACPA). The general use items gap was reduced by 60% on 1 July 2022 and 40% on 1 March 2023. There was another reduction of 10% scheduled for the Part D on 1 November 2023, however the Minister decided not to proceed with this reduction, refer MS23-001508.

Following the post-listing review of surgical guides and biomodels, it is proposed to place the condition on all existing billing codes for these devices, restricting PL reimbursement, specifically: *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.*

s 47G

s 47G [redacted]

Your signing of the MDHTP Rules will give effect to these changes. The MDHTP Rules will repeal and replace the existing *Private Health Insurance (Medical Devices and Human Tissue Products) Rules (No. 1) 2023.*

The Explanatory Statement, including the Statement of Compatibility with Human Rights (Attachment B / TRIM D23-3347249) provides information about changes taking effect in the *Private Health Insurance (Medical Devices and Human Tissue Products) Rules (No. 2) 2023* compared with the existing Rules (No. 1) 2023.

Timing

The Department is committed to make and register the Rules at least 10 working days before the commencement on 1 November 2023 and publish on the Departments website to provide sufficient time for private health insurers and hospitals to update their systems. With this in mind, the PL is expected to be published on the Department's website by no later than 18 October 2023.

The Rules are a legislative instrument and are required to be registered on the Federal Register of Legislation.

Issues/Sensitivities

The information published on the PL is extracted from the Prostheses List Management System (PLMS) (automatically or semi-automatically). Historically there have been occasions of PLMS errors resulting in inaccurate information being extracted and subsequently entered onto the PL (and effectively into the Rules). Correcting the errors requires manual adjustments, and in some cases making amendments to the Rules to ensure the information is correct and complete. To minimise the risk of errors, the Department consults with the sponsors prior to finalising the PL and has implemented internal quality assurance processes.

Consultation

The Department has consulted with sponsors on the draft of the PL. The sponsors' feedback has been incorporated where required and appropriate to do so. The Legal and Assurance Division has provided advice on the MDHTP Rules and has reviewed the Explanatory Statement and the Statement of Compatibility with Human Rights.

A PHI Circular has been drafted and will be published to inform stakeholders of the making of the MDHTP Rules and other related changes and decisions (including reverting 10% benefit reductions for Part D, imposing and changing the conditions, s 47G [redacted] and other changes). The draft of the PHI Circular is provided for your consideration and approval for publication (refer Attachment C / TRIM D23-3494129).

Recommendation

It is recommended that you:

1. MAKE the *Private Health Insurance (Medical Devices and Human Tissue Products) Rules (No. 2) 2023.*
2. APPROVE the Explanatory Statement and Statement of Compatibility with Human Rights.
3. APPROVE the publication of the PHI Circular

s22 [redacted]

s22 [redacted]
Director, Prostheses List Administration Section
18 October 2023

Attachments:

Attachment A *Private Health Insurance (Medical Devices and Human Tissue Products) Rules (No. 2) 2023*

Attachment A.2 Schedule 1

Attachment B Explanatory Statement and Statement of Compatibility with Human Rights

Attachment C Private Health Insurance Circular

DECISIONS

1. **SIGN and DATE** THE *Private Health Insurance (Medical Devices and Human Tissue Products) Rules (No. 2) 2023* (refer Attachment A)

☒ SIGNED / ☐ NOT SIGNED / ☐ DISCUSS

2. **APPROVE** the Explanatory Statement and Statement of Compatibility with Human Rights (refer Attachment B)

☒ APPROVED / ☐ NOT APPROVED / ☐ DISCUSS

3. **APPROVE** the draft and publication of the PHI Circular (refer to Attachment C)

☒ APPROVED / ☐ NOT APPROVED / ☐ DISCUSS

s22

s22, Acting Assistant Secretary
Prostheses List Reform Taskforce
Technology Assessment and Access Division

18 October 2023

s22

From: s22
Sent: Tuesday, 14 March 2023 2:57 PM
To: FLYNN, Elizabeth; s22 ; s22 ; s22
Cc: s47E(d) ; s22 ; s22
Subject: RE: FOR ACTION: NEXT STEPS FOR POST-LISTING REVIEW OF SURGICAL GUIDES AND BIOMODELS [SEC=OFFICIAL]

I think they might see it as outside their brief. There is no suggestion of inappropriate use of MBS items. The issue is whether the appropriately-used MBS item is sufficiently related to use of the prostheses being claimed for as to fulfil PL requirements.
I think this is a policy question for our branch.
The example cited is dental guides. The most common MBS item number is aveolar ridge augmentation, which may occur prior to dental implant surgery (ie getting the jaw ready, so to speak). The 2 are related. There is no suggestion that an alveolar ridge augmentation wasn't done. But implantation of teeth, with or without a guide, is not part of an alveolar ridge augmentation. Indeed there are (almost) no MBS items for dental work.

From: FLYNN, Elizabeth
Sent: Tuesday, 14 March 2023 2:49 PM
To: s22 ; s22 ; s22 ; s22
Cc: s47E(d) ; s22 ; s22
Subject: RE: FOR ACTION: NEXT STEPS FOR POST-LISTING REVIEW OF SURGICAL GUIDES AND BIOMODELS [SEC=OFFICIAL]

I would suggest for 2 (b) that Benefits Integrity and Digital Health Div might be better for referring claims of inappropriate use of MBS Items

From: s22 @Health.gov.au>
Sent: Tuesday, 14 March 2023 1:08 PM
To: s22 @health.gov.au>; s22 @health.gov.au>; FLYNN, Elizabeth <Elizabeth.Flynn@health.gov.au>; s22 @health.gov.au>
Cc: s47E(d) @Health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>
Subject: FOR ACTION: NEXT STEPS FOR POST-LISTING REVIEW OF SURGICAL GUIDES AND BIOMODELS [SEC=OFFICIAL]

Folks

Whilst I realise we need to develop the Department's response to the AHA review findings to determine our policy actions, I wanted to firstly set out the pathway to the Delegate on this matter. I suggest the following:

1. Notify sponsors of review findings – Executive summary of the report – noting this is what will be published on the webpage.
2. Develop the response
    a. Consider appropriate conditions to help shape the use of these products:
        i. Specific MBS items
        ii. Defining terms – simple and complex CMF
        iii. Specific episode of care
    b. Referral to MBD with concerns about non-MBS eligible services being used to claim PL Benefit i.e. dental implants
    c. 2nd year review to determine effect of conditions on usage to determine whether or not there is a need to undertake an economic assessment to address PL benefit issues – this is on the basis that

the technology is fluid and costs are expect to come down along with the broader usage in surgical practice.

3. Notify sponsors of proposed action/outcome
4. Provide Department response and the Report to CAGs
5. Provide Department response and the Report with CAG advice to the PLAC
6. Provide final Minute with recommendations to the Delegate.

I understand that there is a lot more detail underneath each of these points, I have just jotted down key steps and proposed considerations to help conceptualise the pathway.

Appreciate your consideration and advice as to whether or not this is appropriate. Once I have this set, we will work through the timelines so we can schedule the key activities including meeting to discuss the proposed policy settings.

Cheers

s22
Director, Prostheses List Reform Taskforce

Technology Assessment & Access Division | Health Resourcing Group
Australian Government Department of Health
T: s22 E: s22 @health.gov.au
M: s22
Location: Sirius Building s22
GPO Box 9848, Canberra ACT 2601, Australia

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.

Celebrating 100 YEARS OF HEALTH 1921 - 2021
Building a stronger, healthier country
Yesterday today and tomorrow

s22

From: s22
Sent: Friday, 4 November 2022 10:26 AM
To: s22 ; s22
Cc: s22 ; s22 ; s47E(d) ; s22 ; s22
Subject: RE: Update analyses for Surgical Guides and biomodels. [SEC=OFFICIAL]
Attachments: Biomodels and Surgical Guides - 20221031.xlsx

Good Morning all

Many apologies for the delay – please find attached the approved data for updating the tables mentioned below. As with the originally supplied data, the row level data is for internal use only.

Please let me know if you have any questions etc!

Cheers
s22

From: s22
Sent: Tuesday, 4 October 2022 5:10 PM
To: s22 ; s22
Cc: s22 ; s22 ; s 47E(d) ; s22
Subject: RE: Update analyses for Surgical Guides and biomodels. [SEC=OFFICIAL]

Hi s22

I've discussed with s22 and the numbers from the admissions data can probably be updated fairly easily by the end of next week, if you are able to send the updated admissions data, or let me know if there's another way to access.

For the benefit of others, the paper included 2020-21 data from Qlik but the admissions data was up til June 2020.

Kind regards,

s22

Assistant Director – Drug Utilisation Section

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

From: s22 @health.gov.au>
Sent: Tuesday, 4 October 2022 2:56 PM
To: s22 @health.gov.au>

Cc: s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s47E(d) @Health.gov.au>; s22 @health.gov.au>

Subject: Update analyses for Surgical Guides and biomodels. [SEC=OFFICIAL]

Hi s22

I hope DUSC went smoothly last week. As you know we are involved in a review of surgical guides and biomodels for which you did a utilisation review for PLAC (attached with the original data tables). Do you have capacity to update the analyses with 2020-21 data?

In the 2020-21 FY there was a bug jump in utilisation (see below – note 2021-22 data is incomplete). It would be interesting to check if we can see what is driving this in patient level analysis (such as you have done for the 2018-19 and 2019-20 FYs in your original utilisation review). The overall analysis looks like it already included 2020-21 data.

Result Set - SQL Editor 1 (1) | Result Set - SQL E

	FY	PRSTHSS_ITM_C...
1	2018/2019	3,041
2	2019/2020	3,867
3	2020/2021	7,494
4	2021/2022	6,087

We have spoken to s22 in HERD and the 2020-21 data is now complete to use.

Thanks,

s22

s22

Post-market Review Section

Technology Assessment and Access Division | Health Resourcing Group
Office of Health and Technology Assessment Policy and Programs Branch
Australian Government Department of Health and Aged Care
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Work hours: Mon, Tues, Wed 9am-3pm

I acknowledge the traditional custodians of the lands and waters where I live and work, and pay my respects to elders past, present and future.