Private Healthcare Australia
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Prescribed List Post-listing Review of Surgical Guides and Biomodels – Stage 2

PHA Submission

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About Private Healthcare Australia

Private Healthcare Australia (PHA) is the Australian private health insurance industry's peak representative body. We have more than 20 registered health funds throughout Australia as members and collectively represent 98% of people covered by private health insurance. PHA member funds provide healthcare benefits for over 15 million Australians.

Introduction

The massive increase in costs to consumers for surgical guides and biomodels on the Prescribed List (PL) is a policy failure by government that has enabled an entire industry of low value care to emerge. It has cost consumers tens of millions of dollars, which is why it is now incumbent on government to fix it as a matter of urgency.

Private Healthcare Australia first warned the department of the emerging issues with surgical guides and biomodels in 2019. More than five years later, our conservative estimate is over $80 million has been wasted.

PHA notes a small number of engineering start-up entities have seized on the window of opportunity created by the flawed decision to list biomodels and guides on the PL. The department seriously underestimated how these listings could be manipulated for financial gain, including but not limited to, the making of excessive models per patient, and use of these outside of craniomaxillofacial (CMF) surgery when approved (the latter of which was halted after the first stage of the review).

The poor regulatory approach has fostered low-value care, rampant abuse and opened the industry up to potential corruption, with some sponsors allegedly offering payments to providers, making threats to patients, and gouging consumers with outrageously high costs.

All of these problems are for a technology that is, at best, marginally useful in most instances, albeit very important in a few. It is also a low-cost technology with minimal marginal costs of production, which has been paid on a per-unit approach wholly unsuited to the costs and benefits of the technology. In other areas of the PL, these devices have been deemed as not eligible for listing yet are widely used as they are cheap and easy to produce.

The Hereco report states:

> "No convincing data were identified to support the use of patient-matched surgical guides and/or biomodels is more effective or safer than conventional procedures without the use of such devices."

Based on this conclusion, there is no justification for biomodels and surgical guides to be listed on the PL.

PHA notes that some surgeons use surgical guides for very complex CMF procedures, and health funds are willing to continue supporting reimbursement for surgical guides in these complex procedures where there is evidence of efficiency, despite the lack of evidence of effectiveness. This approach is consistent with the first report.

However, the overall waste and abuse with surgical guides and biomodels must stop. Consumers have been ripped off for too long. The department must take action.

Summary of recommendations

Immediate implementation

The Department should immediately implement recommendation A3, remove surgical guides and biomodels for dental implant surgery from the PL. The Stage 1 report recommended removing benefits for simple surgeries, and the Department chose not to implement that recommendation in 2024. This flawed decision prioritised the desires of commercial interests rather than the consumer interest and the public interest.

The second report also found no evidence to support reimbursement for dental implants.

The continued use of surgical guides and biomodels in dental implant surgery is a prime example of low-value care which increases the cost of private health insurance for little or no benefit.

For implementation with six months' notice

Withdrawing benefits for procedures where the evidence is lacking

We note the report's findings (p.5):

> "No convincing data were identified to support the use of patient-matched surgical guides and/or biomodels is more effective or safer than conventional procedures without the use of such devices. This limits the ability to determine whether the current PL benefit for surgical guides and biomodels is relative to the clinical effectiveness."

Benefits for surgical guides and biomodels should be withdrawn where there is no evidence of efficacy or efficiency. If there is no evidence of value, then a device should not be listed, consistent with MDHTAC decisions for new devices. PHA notes the HTA evidence base may emerge with further research. Currently, with these devices already listed, sponsors are actively discouraged from undertaking that research.

Providing simplified benefits for orthognathic (jaw) osteotomies and maxilla and mandibular reconstructions

PHA notes that Hereco has identified weak evidence of efficiency (but not effectiveness) for surgical guides for orthognathic (jaw) osteotomies and maxilla and mandibular reconstructions for both benign and malignant pathologies. Hereco notes that the studies do not specifically identify the benefits of each element of the procedure, but given the complexity and rarity of these procedures, PHA is comfortable accepting that surgical guides are more than likely to improve efficiency for these specific procedures.

These procedures can be identified by MBS items or ICD codes, and PHA supports consideration of the best method of funding the implanted devices and support devices for orthognathic (jaw) osteotomies and maxilla and mandibular reconstructions.

PHA recommends adopting recommendations A8, lowering the benefit of patient-matched implants to be the same as standard implants, and C2, creating a new condition allowing a single benefit for surgical guides or biomodels per procedure rather than per item.

Providing simplified benefits for other complex procedures identified in report one

Report one highlights complex procedures identified by clinicians that are likely to benefit from the use of surgical guides:

- orthognathic surgery (double jaw and complex single jaw – e.g. with segmentation)
- facial trauma surgery
- temporomandibular joint (TMJ) disorder surgery
- cancer resection and reconstruction
- correction of cleft and craniofacial deformities (e.g. craniosynostosis conditions)
- cranial vault reconstruction and cranioplasties
- surgery for rare conditions (e.g. fibrous dysplasia, anodontia)
- dental surgery where it is part of a CMF procedure (e.g. where multiple teeth are replaced as a result of trauma, cancer resection, cleft and palate procedures).

Hereco only identified weak evidence of efficiency (but not effectiveness) for surgical guides for a subset of these procedures, orthognathic (jaw) osteotomies and maxilla and mandibular reconstructions. PHA notes the clinical advice, which does not incorporate clinical evidence, that the other complex procedures on this list may benefit from the use of surgical guides. On that basis, PHA recommends that surgical guides be supported for these procedures on a provisional basis until 1 July 2029 to allow for the collection of evidence suitable for HTA assessment.

PHA notes the lack of an evidence base means if a sponsor of surgical guides applying for PL listing for these procedures, they would be unlikely to be successful. Allowing a provisional, time-limited listing is a significant compromise, recognising the complexity and rarity of these procedures, and the clinical expertise of CMF surgeons.

PHA recommends adopting recommendations A8, lowering the benefit of patient-matched implants to be the same as standard implants, and C2, creating a new condition allowing a single benefit for surgical guides or biomodels per procedure rather than per item.

Background

The original approval for Proplan (now Trumatch) back in 2013 was for a mandated kit that included a matched plate/guide and biomodel unique to a specific anatomical components or injury, some of which were never claimed.

Over time, this precedent morphed into a series of generic plastic components on the PL without volume controls, that were designed in conjunction with a plate from the same manufacturer, and for surgeries with no evidence of HTA value. Surgical guides could and should have had proper condition controls placed on them at the outset to avoid the blowout of low value spending, which has caused consumers financial harm.

This lax regulatory approach has resulted in significant creep in both the use of surgical guides and biomodels, and an increase in the number of plastic components used per surgery. Some of the abuse has been appalling with tens of thousands of dollars in plastic models billed for simple procedures.

The 2019 benchmark, suitably indexed against surgery, would suggest that consumers should be paying between $2.5-3 million for surgical guides and biomodels in 2025-26. Instead, consumers are now paying more than $20 million each year. This is overwhelmingly low value care with no evidence base.

Commentary on recommendations

A1-A3 removing benefits

PHA supports these recommendations and notes the commentary on biomodels not meeting the PL criteria, consistency with other areas of the PL, and removing benefits associated with procedures where clinical effectiveness is not demonstrated.

A4 Establish benefits relative to the clinical effectiveness

PHA supports this recommendation in principle, noting that clinical efficiency (not effectiveness) is only demonstrated for orthognathic (jaw) osteotomies and maxilla and mandibular reconstructions, for both benign and malignant pathologies. Clinical experts assert the benefits of surgical guides for some other complex procedures as listed in report one, but report two could not identify evidence to support those assertions.

The benefits for the use of surgical guides and biomodels in all other procedures should be nil.

There are practical difficulties in clearly measuring the benefits relative to clinical effectiveness for orthognathic (jaw) osteotomies and maxilla and mandibular reconstructions and other complex procedures given the limited evidence to hand.

A5 Align PL benefits for surgical guides and biomodels with the public sector or with internationally reimbursed prices

In most cases, alignment of benefits with the public sector or international prices results in a reimbursement rate of zero. The evidence presented in the second report suggests surgical guides and biomodels are not funded in the public system, and when used globally, are included in the bundled case mix for the operation.

A6 Establish benefits that reflect the cost of production of surgical guides and biomodels

In a significant understatement, the second report notes: "the cost of materials and 3D printing of surgical guides and biomodels is modest relative to the PL benefits." The report notes there is a small cost for producing the first model and a negligible cost for subsequent plastic models produced from the same processes.

Our calculations from market experts align with Ballard's on the cost to set up production. However, while Ballard could show this to be cost effective for each hospital to make their own models using their own staff/3D printers, this is a long way from the model on the PL today. As such, we consider this to be unworkable in the short-term giving the heterogeneity of hospitals performing orthognathic (jaw) osteotomies and maxilla and mandibular reconstructions, and other complex CMF procedures.

However, the benefits for plastic models used for these procedures should consider the low marginal costs of producing these models within this context.

A7 Establish benefits for surgical guides and biomodels that are proportionate to other costs associated with the implantation procedure

The current settings for the PL allow six plastic models for dental abutments, which provides payments of up to 50 times the cost of the implant [$171] positioned by the surgical guides. This is an outrageous abuse and is clearly low value care – most abutments are put in without the need for thousands of dollars of plastic models.

The second report notes there is a small cost for producing the first model and a negligible cost for subsequent plastic models produced from the same processes.

As the benefits for most procedures cannot be demonstrated, the premise of this recommendation – that there is value in the plastic models – is rejected. For orthognathic (jaw) osteotomies and maxilla and mandibular reconstructions and other identified complex CMF procedures, PHA recommends a single benefit, taking into account the costs of production and the benefits of the procedure.

A8 Lower the benefit of patient-matched implants to be the same as standard implants

PHA supports recommendation A8. This increases consistency across the PL, with CMF patient specific devices assessed in line with the approach taken by MDHTAC and clinical advisory groups in relation to hips, knees and spinal devices where the lack of evidence that patient-specific devices offer a superior outcome result in them obtaining the standard benefits.

Recommendations B1, B3-6

These recommendations are not supported, with the second report highlighting the weaknesses of each approach.

Recommendation B2 A single benefit for surgical guides or biomodels per procedure rather than per item

PHA supports option B2 for orthognathic (jaw) osteotomies and maxilla and mandibular reconstructions and other identified complex CMF procedures.

PHA has been advised by multiple clinicians that access to digital surgical planning is more valued in preparing for the case and implant positioning than the output of multiple plastic models.

As the second report highlights, planning is the major cost input in the development of custom plates, surgical guides and biomodels and occurs at the procedure level rather than the device level. Restricting to a single benefit payable per procedure would reflect the additional value of using VSP to produce plates and plastic aids required for that procedure. The marginal cost of producing additional plastic models is negligible.

The original Proplan approval was a procedure kit where the components of models/plates were anatomy specific and in natural ratios. A single benefit for the device and any ancillary support, be it digital planning and/or production of plastic models, is viable for orthognathic (jaw) osteotomies and maxilla and mandibular reconstructions and other identified complex CMF procedures.

PHA does not support the addition of the current biomodels/guides (x 6 per patient) on top of the elevated prices of the currently approved 3D patient specific plates to form a kit price. The second report clearly highlights the inflated pricing at each stage of the process, which contributes to higher premiums for consumers.

Recommendations C1-3

The recommendations for re-grouping of items (C1 and C2) are based on an assumption that models/guides should be retained. If there is no quantifiable evidence to support their value, then retaining them on the PL and resetting how and where these are recorded cannot be justified.

PHA and member funds have asked the Department multiple times whether splints are approved on the PL. The responses have consistently highlighted that these items have never been assessed. There is no obvious merit in placing these items on the PL. The use of splints is common in dental practice and the cost in the market is a tiny fraction of the PL benefits.

Conclusion

The continued listing of biomodels and surgical guides under the current arrangements makes a mockery of the PL being based on evidence and providing a consumer benefit. It is inconsistent with other regulatory approaches by the Department, and also inconsistent with other areas of the Prescribed List.

The integrity of the PL relies on a consistent, evidence-based approach that prioritises the needs of consumers over the commercial aspirations of device sponsors. This is particularly so where the market opportunity for some sponsors has been entirely created by poor regulation and enforcement.

PHA recommends a final resolution would be for a 3D patient specific plate and all digital support models and planning to be at or below the current rate for the 3D plates alone, and only for orthognathic (jaw) osteotomies and maxilla and mandibular reconstructions or complex surgeries where they may offer value, as identified in report one.