AUSTRALIAN MEDICAL ASSOCIATION
ABN 37 008 426 793
T I 61 2 6270 5400
F I 61 2 6270 5499
E I ama@ama.com.au
W I www.ama.com.au
39 Brisbane Ave Barton ACT 2600
PO Box 6090 Kingston ACT 2604

SUBMISSION

Thursday, 3 April 2025

AMA submission to the Department of Health and Aged Care on the post-listing review of surgical guides and biomodels Stage 2 draft report

By email: prescribedlist.reviews@health.gov.au

Introduction

The Australian Medical Association (AMA) is pleased to provide a submission to this consultation.

However, we are concerned that the Department of Health and Aged Care initially gave stakeholders only two weeks to digest the contents of a 92-page report and provide feedback. Although the AMA appreciates the fact that following representations from us and other stakeholders, the department granted an extension of an additional two weeks to respond, such representations should not have been necessary.

Other recent Prescribed List (PL) consultations, such as the 'Clarifying definitions under the current grouping scheme' consultation released just before Christmas without prior notice, have also provided unacceptably short time frames for lodgement of stakeholder responses. This amounts to very poor consultation practice and casts doubt on whether the PL is being appropriately governed.

Feedback on the Stage 2 draft report

Overview

The AMA is also concerned about several aspects of Hereco's draft report on Stage 2 of the post-listing review (PLR) of surgical guides and biomodels (SGBM) — in particular, the fact it exceeds the scope of the terms of reference for the Stage 2 review.

The terms of reference for the Stage 2 SGMB PLR asked Hereco to provide 'recommended actions and outcomes about appropriate benefits [for SGBMs] for consideration by the delegate'. However, Hereco appears to have gone beyond this by including proposals to remove SGBM from the PL and/or further restrict their use. These issues were addressed

during the Stage 1 review. Hereco also includes options with respect to the listing and benefits for patient-specific implants, which were also out of scope for the review.

As stakeholders were not given an opportunity to submit relevant data in relation to patient-specific implants, the AMA believes any options or recommendations Hereco makes with respect to them must be ignored until appropriate stakeholder consultation on these items has occurred.

Under PL reforms and the Memorandum of Understanding between the federal government and the Medical Technology Association of Australia (MTAA), there is already a process for setting benefits for SGBMs using public price referencing, which (as noted in the draft report) has already resulted in substantial reductions to the benefit levels for SGBMs, most particularly surgical guides.

Relatively new and innovative products cannot hope to have the same level or quality of comparative cost-effectiveness data as long-established products on the PL. However, that is no reason not to list them on the PL if, as in this case, most relevant studies find they have patient benefits in more complex surgeries, such as shorter operating time, and clinicians find them safe, effective, and easier to use than older methods/technologies in complex or unusual clinical circumstances.

In other specialties such as orthopaedics, surgeons regularly use CT-based planning, modelling or analysis of planned procedures with associated production of guides and biomodels that are not funded by the PL. Although these technologies were initially only used for the most difficult cases, clinical practice has moved on because surgeons have realised they can improve surgical accuracy and reduce surgical time even in relatively simple cases (especially as costs have reduced).

However, these advantages are very difficult to capture in studies, because the clinical outcomes of a poorly executed osteotomy, for example, may not be measurable for some years after the surgery.

In the case of SGBM currently listed on the PL, the AMA suggests that given the circumstances, the public price in Australia, which reflects a competitive market, should be the default PL benefit (that is, Option A5 presented in the draft report). None of the other options provided by Hereco appear justified on the evidence presented in the draft report.

Options for benefit setting

As the report itself notes, many of the options for setting benefits presented in the draft report are likely to be unworkable. Many of them also restrict clinician choice and place patient access to these items in the private sector at risk, either because costs will be passed on to patients, or because the products may be withdrawn from the market if remuneration is inadequate.

This will result in some surgeries being pushed into the public sector and seems most unfair to privately insured patients, given they often pay for private health insurance because they want the benefit of the newest technologies.

The draft report notes surgical guides in the orbital category did not have a reduction in price under PL, while guides in the other two categories did see price reductions. This is to be expected, given guides in the orbital category are needed relatively rarely in specific clinical circumstances, so public prices have not been driven down by volume of use. This simply means these items do not add a great deal to insurers' costs. It does not provide a valid reason to throw out the public price comparison methodology altogether.

Comments on specific proposals

A1: Remove biomodels from the PL

This was settled in the Stage 1 PLR and is out of scope for this review. The draft report is also incorrect in reducing biomodels to a by-product of patient matched implants; the AMA understands some hospitals that do not supply patient matched implants make biomodels in-house.

A2: Remove SGBM from the PL

This was also settled in the Stage 1 PLR and is out of scope for this review. In addition, by removing reimbursement via the PL, this option would restrict access by passing costs on to private hospitals or patients and increase demands on the public hospital system.

A3: Remove SGBM for dental implant surgery from the PL

This was also out of scope for this review.

A4: Establish benefits relative to the clinical effectiveness of SGBM

As noted in the draft report, this option cannot be implemented as the required evidence is unlikely to be generated for these devices.

A5: Align PL benefits for SGBM with the public sector or with internationally reimbursed prices

As mentioned earlier, aligning prices with Australian public hospital prices is the AMA's preferred option.

The draft report notes the relatively low price paid by insurers for these items in the US, but fails to mention that in the US, patients pay the considerable gap between what insurers pay and the market price of the relevant devices.

A6: Establish benefits that reflect the cost of production of SGBM

Hereco argues that a benefit established on the basis of published costs for in-house facilities, with an additional commercial profit margin, would be substantially lower than the current benefit.

They would be, but the argument that it would be fair to establish benefits based on the published costs of production for in-house facilities reflects a misunderstanding of the nature of the SGBM devices currently used by clinicians. Firstly, the costs of production of simple 3D plastic models are low; the real cost is segmenting CT data, developing 3D models (some of which use proprietary technology), and communicating with the surgeon to perform the surgical planning, all of which involve time and considerable expertise to ensure the accuracy of the product.

Secondly, not all SGBM currently in use can be replicated by in-house 3D printing. The AMA understands titanium guides are the industry standard for orthognathic surgery as they permit a less invasive approach than plastic guides, which are thicker and bulkier.

A titanium printer costs about AUD $1.5–2 million and the quality of what it produces cannot be compared to the products of an AUD $4,000 desktop plastic printer. Polyamide printers for models and guides cost about AUD $275,000.

Many private hospitals are unlikely to be able to afford outlays like these.

The AMA understands titanium printing also requires a 'safe room' and post-processing equipment, and that the raw material cost of titanium powder is higher than acrylic or nylon polymers.

A7: Establish benefits for SGBM that are proportionate to other costs associated with the implantation procedure

As the Hereco draft report notes, this option would need a complex mechanism to account for heterogeneity of use and surgical complexity, which would be extremely difficult to implement.

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

Neither patient-matched implants nor a comparison of CMF patient-matched implants with those listed elsewhere on the PL were within the scope of the terms of reference for this review.

This proposal also seems to conflate two different things — virtual surgical planning and the cost of design and production of implants.

Options for placing conditions on benefits payable for SGBM

Option B1: Retain the conditions recently imposed on the maximum number of SGBM that can be used per procedure

The draft report rightly acknowledges this approach has a greater impact on complex surgeries than on simpler procedures, which is a concern if the evidence of the greater value of these particular SGBM in complex procedures cited in the draft report is correct.

The AMA does not support retention of this condition. The decisions of clinicians on the number of SGBM required to address the needs of individual patients and specific clinical circumstances must be respected and paid for by insurers.

Option B2: Create a new condition allowing a single benefit for surgical guides and biomodels per procedure rather than per item

The AMA does not support this option, for the same reasons given in relation to Option B1.

Option B3: Implement a stratified approach where benefits payable for SGBM are reduced for each additional product used

The AMA does not support this option, which as the draft report notes, risks higher out-of-pocket costs for patients undergoing more complex CMF surgeries.

It is also unclear how the value of the billing code could be manually adjusted for each patient.

Option B4: Implement a tiered approach where benefits payable for surgical guides and biomodels are higher for more complex surgeries

The AMA does not support this approach, which is unprecedented and would be very difficult to implement, even with significant clinician input. It is also likely to result in higher out-of-pocket costs to patients for 'simpler' procedures.

B5: Create a condition that SGBM only attract a benefit when used without a patient-matched implant

The AMA does not support this option, which stands in direct contradiction of the PL requirement that benefits for SGBM are only payable where they are essential for successful implantation of the implant.

Options C1 – C3: Options for potential regrouping of SGBM on the PL

The AMA does not have strong objections to Options C1 and C2. However, as Hereco itself notes in its draft report, Option C3 is impractical, as due process would necessitate all sponsors resubmitting applications for respective devices for ECAG consideration.

Concluding comments

The AMA wishes to draw attention to the fact that this consultation affects only a small proportion of the SGBM in routine use by clinicians in Australia, because most of them are not currently approved for listing on the PL. The use of these technologies is now routine across numerous specialties, but the PL appears to be lagging current practice.

One result is that these technologies not on the PL are funded by either the patient, the hospital, the implant manufacturer, or very rarely, through ex-gratia payments from insurers. Another result is that in orthopaedics alone, there are now several procedures that are easier

to perform in public hospitals than in private hospitals, because the required devices and technology are available for surgery in public, but not private hospitals.

Given the PL is supposed be the funding mechanism for privately-insured patients who pay large private health insurance premiums and need surgery or procedures that require the use of medical devices or human tissue products, we have to ask if these outcomes are appropriate.

The AMA believes great care must be taken to ensure that the reforms to the Prescribed List being advocated by insurers do not have the unintended consequence of putting the private health sector in a disadvantaged position compared to public hospitals, further undermining the value proposition of private health insurance.

Contact

president@ama.com.au