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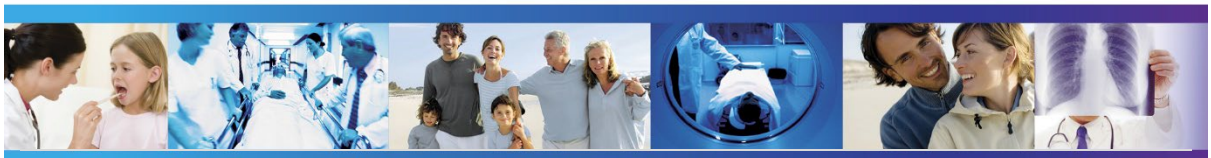

Prescribed List Reforms - Consultation Paper 10: General use items

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About Private Healthcare Australia (PHA)

Private Healthcare Australia (PHA) is the Australian private health insurance industry's peak representative body. We have 22 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 14.4 million Australians.

Introduction

General use items on the Prescribed List of Medical Devices and Human Tissue Products (the PL) include a range of items that are not specific to a particular surgical procedure.

Private Healthcare Australia was disappointed in the government's decision to keep general use items on the Prescribed List of Medical Devices and Human Tissue Products (the PL). As the independent report from EY noted, bundled funding arrangements are a more appropriate mechanism for funding general use items.

PHA's greatest concern is that the government's decision will again see an increase in patient costs with no improvement in outcomes. The EY report noted that costs to consumers for general use items increased by more than 9% per annum during a five-year period where surgery rates were flat, with no measurable improvement of patient outcomes. The report noted that there was no natural limit to the number of general use items that can be used, and unlike most other items on the PL, there is no auditable evidence that these items are actually used, as they do not show up on an X-ray.

In addition to the core finding that these items should be removed, the EY report highlighted key integrity issues that the government should now address to protect consumer welfare.

The EY report observed:

- "Increased usage per separation – the increase in usage was not only driven by increased numbers of procedures. Specific examples include Staples & Tackers (03.08.04), Internal Adhesives (03.08.02), Infusion pumps (03.02.03), Powder (03.05.02) and Matrix (03.05.05) items.
- Usage tended to be very skewed towards more expensive types of items, even though it could be expected that for a reasonable proportion of these procedures a cheaper version would be clinically sufficient (for example, there was a consistent large skew towards the usage of larger volume/area items rather than

smaller items). Specific examples included Internal Adhesives (03.08.02), Pliable Patches (03.05.04) and Matrix (03.05.05) items.

- Usage of some items grew suddenly following listing, potentially indicating that the growth was driven by its availability on the PL and not due to changes in clinical needs."

PHA's major concern is volume and cost being added with no demonstrable clinical benefits. For example, there was a 12.9% volume growth in general use items in 2017/18 on flat surgery volumes. Overall, the costs of general use items in many categories doubled over five years. For example, internal adhesives, which includes external skin glues, and matrix products increased in cost to consumers from $27.2 million in FY 2014 to $73.3 million in FY 2019. There are no data suggesting patient outcomes improved over this period.

After careful consideration of the EY report and examining claims data, PHA includes a list of areas where errors could be corrected, or integrity issues identified by EY could be addressed. PHA has a range of recommendations to improve integrity and ensure that growth in utilisation and expenditure is matched by demonstrable outcomes for patients.

Recommended general actions

Price/volume agreements

EY reported, "[some] GM items were experiencing high growth in aggregate: beyond the growth in the number of procedures being performed and at a level suggestive that there may be inefficiencies and overuse."

PHA recommends that the PL introduce price/volume agreements for general use items, based on the PBS model. For example, if the total use of items under each subcategory increases by more than 10% in any year (adjusted for any increases in surgical volume), the price of all items under that code should be reduced by 10% (rounded up to the nearest dollar).

This would ensure that consumers are not penalised where usage increases unexpectedly. Increases in usage may be the result of changes in clinical practice, and the Government should then undertake a health technology assessment (HTA) to determine if the increased costs to consumers is worth the additional benefits to patient care.

No out-of-pocket costs as a condition of listing

While health funds are forced by law to pay the PL benefit, there is no commensurate obligation on sponsors of medical devices to ensure patients are not subjected to out-of-pocket costs. It is not reasonable to allow MedTech companies to collect a benefit enforced by law, and then allow them to charge whatever they like above that benefit. In practice, this is rarely an issue, but PHA recommends that a condition of listing be introduced for Part D of the PL that companies commit to ensuring the price of supply to hospitals does not exceed the PL benefit.

All price increases should demonstrate a public benefit case

Where an item on the PL increases in price, for example, through the sponsor seeking a higher price through an amendment application (changing the grouping), the government should demonstrate the public interest case to the community, including the clinical and economic benefits. These public interest cases should be published by the Minister each PL cycle.

The EY report highlighted: "There was clear evidence of significant increases in benefit amounts for items in long-standing use [where the items] have not changed. In each case, usage increased following the increase in benefit amount." Consumers in these instances are penalised twice, through higher prices and higher volumes.

Providing feedback to clinicians

PHA agrees a national index that benchmarks the usage per episode of care (based on the IHACPA bundled benefit work) would provide a reasonable measure from which to determine actions to adjust the PL benefits per grouping. These data should also be provided to hospitals and clinical societies to improve education.

Hospitals and clinical societies should inform clinicians of the prices of common PL items, to ensure that doctors are able to make clinical decisions with an understanding of the cost of their decisions. Many data demonstrate that doctors who are informed about the costs of health care are more likely to make decisions to avoid low-value care.

Hospital groups, including Catholic Healthcare Australia and the Australian Private Hospitals Association, have previously offered to provide feedback to clinicians.

Addressing outliers

Where hospitals use general use items at a significantly higher rate than their peer group (for example, over 20% to 50% higher than the average), rebates should only be provided in full where the treating doctors certify that the unusual use is reasonable and

necessary. Otherwise a 120% to 150% expenditure cap should apply, depending on the variations in clinical practice.

This will encourage hospitals and clinicians to examine their usage compared to their peers, while ensuring that funding is available where treating clinicians consider it reasonable and necessary.

Remove suffices which do not impact on patient outcomes

Several items in Part D of the PL include suffices which are based on the characteristics of the device, and do not impact on the patient outcome. Removing these suffices would include price reductions. Attachment A includes a list of suffices to review. These should be assessed by clinical experts to determine if the device characteristics identified affect patient care, and if so, what premium is appropriate.

Improving integrity

The EY report highlighted a number of areas where they noted significant variations in billing practices that did not appear to be based on clinical need.

Each of the suggestions below are designed to be cost-neutral, but address some of the gaming issues identified by EY.

Remove capital items

Part D of the PL includes a number of infusion pumps, which are capital items. EY noted, "It is clear that infusion pumps cannot themselves be considered surgically implanted due to their function external to the patient's body." Further, EY demonstrated that pumps were often charged to patients who never used them; "Conversely … infusion pumps are often used without another implantable device on the PL."

Infusion pumps are used by many patients, yet billed to one. This is unfair on the consumer and health fund that end up paying the costs for several subsequent patients. Further, there is no limit on the number of pumps (at substantial cost) that can be billed, providing an incentive to bill more pumps than necessary. EY noted, "A disconnect between the usage of Infusion Pump Accessories (03.02.05) and Infusion Pumps (03.02.03) whereby high growth in the usage of accessories was not mirrored in associated pumps."

PHA recommends that the department remove capital items for infusion pumps (03.02.03) and increase cassette cost (03.02.05.02) to compensate. Increasing the cost from $26 to $50 would result in no net financial impact for health funds and suppliers.

Removing the capital items would also provide competitive tension, where suppliers would have an incentive to provide pumps at no cost to hospitals as a loss leader for the sales of cassettes.

Remove topical skin adhesives

The government has committed to maintaining Part D of the PL, but has not committed to keeping every item on the list. As highlighted in the EY report:

> "There is evidence of items being included on the PL in sections which may be inconsistent with their actual or intended use. Of particular note is the inclusion of topical skin adhesive products in the '03.08.02 – Internal Adhesives' group, as part of the '03.08 – Closure Devices' subcategory. These products were identified in stakeholder submissions and from product descriptions as being intended for use on the surface of the skin and it is consequently questionable whether they should be considered as 'internal adhesives'...
>
> "Furthermore, there may be reasonable grounds to question the fulfilment of the listing criteria for these topical skin adhesive products. As a product intended to be used on the surface, it appears that such topical skin adhesives cannot be claimed to be "surgically implanted" and so cannot meet [the listing criteria]".

These items can be used anywhere, cannot be tracked, and in a two-year period increased in consumer cost from $3 million to over $15 million.

Topical skin adhesives are not internal adhesives, and should be removed from the PL.

Move to single prices for pliable patches and absorbable sponges

PHA recommends that the prices for pliable patches and absorbable sponges be consolidated into a single price rather than different rebates for different sizes.

The EY report noted, "Differential use of higher cost items when a cheaper alternative is available suggests that the PL may not adequately disincentivise the use of items that perform clinical roles in excess of what is required. Various case studies suggest that this occurred within the 'High' priority GM category."

For pliable patches, EY observed, "that usage per separation did not increase significantly for this group since FY14. However, it is apparent that usage of the smaller sized patches decreased alongside significant increases in usage of the two subgroups of larger sized patches. As a result, total benefits for the group increased faster than utilisation due to the growth in utilisation being greater in the more expensive versions. This is reflective of how significant differences in the benefit amounts per item between similar products can lead to higher benefits being paid than might otherwise be

necessary. This is due to a lack of disincentives against usage of larger size patches in cases where the smaller patches may be sufficient."

Further, EY noted significant differences between hospital groups, which may indicate that hospitals are promoting the use of more expensive products to increase rebate income from suppliers. EY concluded, "The large differences between these two hospital groups, performing a large number of a wide range of procedures, may be suggestive that the additional usage of the larger size may not be driven purely by clinical need."

As pliable patches are relatively cheap to produce a single price is feasible and would help address the incentives identified by EY towards the larger sizes of the product.

The same arguments apply to absorbable sponges, which should also move to a single averaged price.

These changes would have no net financial impact.

In addition to removing perverse incentives for use, single prices for patches and sponges would improve administrative efficiency.

Move to a per gram price for haemostatic power

PHA recommends the PL utilise a per gram price for haemostatic power to remove incentives for larger sizes. Again, the price could be set to ensure no net financial impact.

Haemostatic powders are mispriced currently, with incentives to use larger sizes. This likely results in significant wastage and additional costs, as larger packets are opened and only a proportion of the product is used. A per gram price flips these incentives, to reduce waste and additional cost.

Merging percutaneous catheter prices

There are minor differences in pricing for items under 10.09.01 - Percutaneous Catheters, Single Lumen, and 10.09.02 - Percutaneous Catheters. PHA recommends the department consider merging all the items under each category, removing all suffices and averaging the price (with no net financial impact).

Introducing an enforceable code of conduct

PHA recommends the Australian Government introduce an enforceable code of conduct for the medical device industry as soon as practicable, using the pharmaceutical code as a guide. There is no policy justification for medical devices and

pharmaceuticals to be treated differently, and significant public benefit in an enforceable, transparent code of conduct.

Fixing mistakes on the list

Part D of the PL includes a number of errors that total around $6 million per annum in unnecessary spending. As Part D is being retained, these errors should not be tolerated and addressed immediately to improve the integrity of the PL.

Errors identified by PHA include:

- All adhesion barriers with the same ARTG should be priced at the public reference price for the dominant item used in the public system. Currently, adhesion barriers in the public system are half the price of the private system despite being essentially the same product with the same ARTG listing.
- Reprice Floseal and Purastat 5mls to the equivalent of Surgiflo 6ml. There is no justification for a higher price for a lower volume of a similar product.
- Hemoblast VB002 reduced to same price as Floseal and Surgiflo. There is no justification for a higher price for a lower volume of a similar product.
- Applicators (03.05.05.05 - Accessory Extender) should be removed from the PL, as they should be incorporated into the primary device. In some cases, they are packaged in the same box.
- Move ET082 PureRegen Gel Sinus from adhesion barriers to nasal code (no price impact).
- Internal adhesive applicators (03.08.02.04 - Adhesive Accessory) should be removed from the PL, as they should be incorporated into the primary device. In some cases, they are packaged in the same box.
- Remove ET065 as it is a suture and not eligible.
- Remove ET066 as it not eligible, it is a skin stapler.
- Tristapler MI287 and GIA stapler AS209 should be repriced to the sum of the component parts.
- Remove CoreKnot products, as these are surgical instruments (DE606, DE609)
- Remove the anomaly where larger sponges receive much higher remuneration, change to per cm for all sizes.
- Reprice all liquid repair sealants to the highest volume price, rather than paying more for the smaller sizes.
- Place condition on use for all liquid repair sealants to dura, as per the Indications for Use documents.
- ER279 OverStitchTM Endoscopic Suturing System should be repriced to the comparator FQ002.

Recommended price reviews

Integrity of the PL is damaged where consumers pay more than necessary for medical devices. Several categories of staplers in Part D of the PL have price premiums where there has been no HTA to justify the additional costs to consumers. These additional costs – over $13 million per annum – have been imposed on consumers based on the characteristics of the device and claimed benefits which have never been tested. PHA recommends that HTA assessments be undertaken for the following groups:

- Powered staplers
- Endoscopic suffices for staplers
- Staplers, Non-bone with Disposable Applier.

A premium may be justified, but there is no clear benefit to consumers of these items over standard staplers. These additional costs should be assessed, and reduced or eliminated if additional patient benefit is not demonstrated.

Attachment one: Suffices to review

While professional advice is required, these suffices appear to be based on the characteristics of the device rather than an effect on patient care.

For example, stapler reloads are similar regardless of the type of stapler, there is unlikely to be a need for a suffix and additional payment.

03.02.02 - Infusion Pumps, Balloon Based		03.02.02.01 - Fixed Flow Rate	Bolus
03.05.03 – Sponges		03.05.03.01 - Absorbable ≤75cm²	Anatomically Conforming
03.05.03 – Sponges		03.05.03.01 - Absorbable ≤75cm²	Low Antigenicity
03.05.03 – Sponges		03.05.03.02 - Absorbable >75cm²	Low Antigenicity
03.05.04 - Pliable Patches	03.05.04.01 - Absorbable ≤50cm²	Antimicrobial, Low Antigenicity	
03.05.05 - Matrix	03.05.05.02 - Liquid >6ml	Complete Biomaterial	
03.08.03 - Ligating Devices		03.08.03.01 - Clips	Polymeric Non-resorbable
03.08.02 - Internal Adhesives		03.08.02.02 - Adhesive >2-5ml	Biological
03.08.02 - Internal Adhesives		03.08.02.02 - Adhesive >2-5ml	Synthetic
03.08.03 - Ligating Devices		03.08.03.03 - Clips with Disposable Applier	Laparoscopic
03.08.03 - Ligating Devices		03.08.03.03 - Clips with Disposable Applier	Open
03.08.04 - Staples & Tackers		03.08.04.01 - Staples, Non-bone (Reload)	Curved
03.08.04 - Staples & Tackers	03.08.04.01 - Staples, Non-bone (Reload)	Endoscopic, Articulating/Roticulating	