Review of the General Miscellaneous Category of the Prostheses List

Department of Health

31 July 2020

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1. Executive Summary

1.1 Background and approach

1.1.1 General Miscellaneous items on the Prostheses List

Background

The Prostheses List (PL) is a legislated list of prosthetic items and associated benefit amounts. It requires private health insurers to pay for prostheses that are provided to a privately insured person as part of an episode of hospital treatment. In doing so, it guarantees that private health insurers (insurers) will pay hospitals a set amount for every item used, with the intention of ensuring that patients have access to safe, clinically effective and cost effective prosthetic items.

There are around 11,000 items on the PL, representing the diverse nature of prosthetic items available to clinicians. These are separated into 13 'categories', one of which is the '03 – General Miscellaneous' (GM) category.

The GM category includes a wide range of surgical items which can be grouped into two broad types:

- Prosthetic items that are designed for a specific purpose which is central to certain types of surgical procedure, but that do not fit neatly into the other 12 categories of the PL. Brachytherapy and gastric band devices are examples of these '**miscellaneous**' items.

- Other medical items which are used to support a range of different types of surgical procedure which are either inserted into the body or assist other items that are inserted into the body. Drug delivery devices, haemostatic devices and closure devices are examples of these '**general**' items.

Listing criteria

The criteria for an item to be included on the PL are included in the Prostheses List Guide (the Guide), which is maintained by the Australian Government Department of Health (the Department).

Criterion 4a of the Guide is the key requirement for most items to be included on the PL:

4a: A prosthesis should be surgically implanted in the patient and be purposely designed in order to: replace an anatomical body part; or combat a pathological process; or modulate a physiological process.

Criteria 4b and 4c of the Guide allow some other items to be included on the PL that are not themselves implanted, so long as their use relates to items that are implanted:

4b and 4c: A prosthesis should be essential to and specifically designed as an integral single-use aid for implanting a product, described in 4a, which is only suitable for use with the patient in whom that product is implanted; or be critical to the continuing function of the surgically implanted product to achieve (i), (ii) or (iii) above and which is only suitable for use by the patient in whom that product is implanted.

Usage issues

The GM category of the PL saw significant increases in utilisation and total benefits paid each year over the period from FY14 through to FY19. In this period, there was an 11% compound annual

growth rate (CAGR) in the number of items used per year and a 9% CAGR in the total benefits paid over the period. More recently, from FY18 to FY19 the growth in utilisation of items in the GM category was 15%, although the corresponding growth in total benefits paid was lower, at 3%. The lower average benefit amount paid per item was partly due to benefit amount reductions and partly from high usage for new lower benefit amount items.

The concern which is the basis for this review is that using PL as a funding mechanism (which guarantees that insurers will pay a set amount for every item used) for low cost high usage items may not send a direct price signal to the clinicians and hospitals, and so:

- Usage of the item over and above the minimum level necessary to ensure appropriate patient outcomes is not disincentivised; and/or
- There may be higher than necessary usage of more expensive versions of equivalent products, including when they provide little/no clinical benefit over cheaper alternatives.

As a result, EY was instructed by the Department to focus the review on the following 'general' GM items, which are typically low cost but high usage items that can be used to support a wide range of surgical procedures:

- drug delivery devices (the 03.02 sub-category of GM);
- haemostatic devices (the 03.05 sub-category of GM); and
- most closure devices (the 03.08 sub-category of GM).

By assisting in the administration of drugs, controlling bleeding and repairing wounds, these items clearly perform clinically necessary roles. However, their functionality can be required in a wide range of procedures not normally associated with prosthetic implantation and are usually only required as a secondary consequence of the procedure itself. Also, for haeomostatic and closure devices, these functions can often be performed by other items not funded through the PL (for example, sutures, swabs, sponges, dressings, most catheters, scalpels).

For the purpose of this review, these items have been termed 'High' priority GM items and the following figures show the total number of PL items used and total PL benefits paid for the GM category from FY14 to FY19, split by the contribution from the 19 'High' priority groups and the remaining 'Low' priority groups.

Figure 1 – GM – Total Prosthetic Items

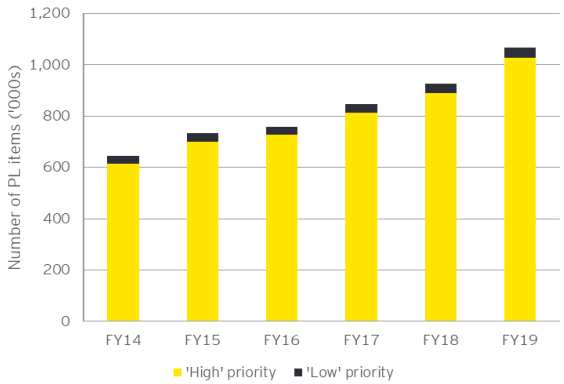
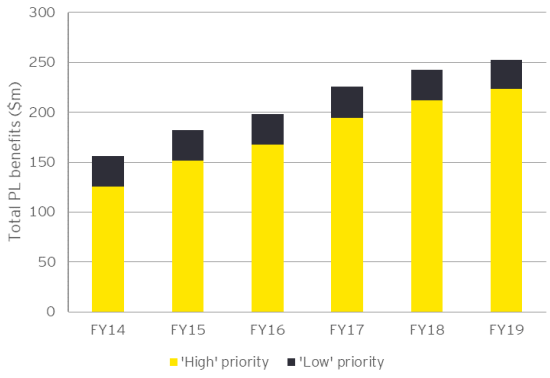


Figure 2 – GM – Total Prostheses Benefits



This review

It is possible that system efficiencies could be gained by removing these low cost high usage items from the PL and funding them through alternative mechanisms – most likely through case based or bundled payments, for example Diagnosis-Related Group (DRG) based payments or banded theatre fees relating to the nature of the procedure being performed under the National Procedure Banding schedule. The precise mechanism by which insurers then reimburse these fees would depend on the arrangements between insurers and hospitals. Theatre fees are intended to include consumables and disposable instruments.

EY was engaged by the Department to undertake this review of the GM category of the PL. The Terms of Reference for the review were to:

1. Consider whether items listed in the GM category meet the current criteria for listing of prostheses on the PL as set out in legislation and guidance documents. Issues with the listing criteria and categorisation approach are investigated in detail in Section 4.3.

2. Examine Hospital Casemix data to identify trends in use and expenditure in the GM Category. Cases of high and/or highly growing usage are investigated in detail in Section 4.4.

3. Consider whether items listed in the GM category are also funded through other private health insurance payments. In Section 4.6, it is considered whether alternative (non-PL) funding mechanisms are available for the same items analysed in Sections 4.4 and 4.5. Recommendations relating to whether the use of these mechanisms might have the potential to reduce overall costs are included in Section 6.2.1.

4. Consider whether for reasons of improved efficiency, items in the GM category should be removed from the PL and funded by private health insurers through other mechanisms, which is also considered in Sections 4.6 and 6.2.1.

5. Consider whether there would be unintended consequences should any items in the GM category be removed from the PL, which is also considered Sections 4.6 and 6.2.1.

6. Consider whether any items listed in the GM category should undergo a health technology assessment to determine their comparative value. Issues relating to benefit amounts are investigated in detail in Section 4.5.

The purpose of this review was to:

- identify items where there may be a case for changing the listing, price, funding and/or funding arrangements;

- discuss the potential implications of identified changes; and

- develop a list of recommended next steps for consideration by the Department.

1.1.2 Approach

EY performed a desktop analysis of relevant legislation and guidelines, as well as literature on the clinical function of relevant PL items.

Prior to detailed usage analysis being performed, the Department sought initial input from private health insurers, hospitals and other registered parties via a Private Health Insurance (PHI) Circular on

the appropriateness of the PL for funding GM items. This feedback provided useful contextual and qualitative information that directly informed the findings.

The analyses and preliminary findings were also discussed with EY's clinical subject matter resources (SMRs).

The detailed usage analysis centred on interrogating the Department's Hospital Casemix Protocol (HCP1) dataset to understand trends in usage of GM items on the PL. Analysis was performed on the situations in which GM items were used, including: the types of surgical procedures they were used in; whether other PL items were used in the same procedure; the hospitals where the procedures were performed; and demographic information relating to the patient.

Planned additional rounds of consultation on specific observations from the usage analysis, and a presentation of draft findings to the Prostheses List Advisory Committee (PLAC), were not possible due to the onset and impact of COVID-19 on the health industry in Australia during the preparation of this report.

1.1.3 Purpose of this report

The intention of this review was to identify items where there may be a case for changing the listing, benefit amount and/or funding arrangements for certain low-value, high-volume items listed in the GM category by presenting evidence and commentary on specific items with consideration around whether their inclusion on the PL is fit for purpose.

This report provides recommendations for consideration by the Department. It is possible that broader changes to the way that the overall PL works might either indirectly address the problems identified or make the recommendations ineffective. As such, it is important that the recommendations should be considered in the context of any potential other changes to the PL.

It is also worth noting that, while the recommendations only apply to certain GM items, there may be other non-GM categories with similar issues. As such, the overall consistency of the PL should be considered prior to any recommendations being implemented.

1.2 Findings and next steps

The findings have been grouped into issues and then the causes of those issues. A summary of the next steps, including recommendations for consideration by the Department, is then provided. These findings and next steps have been constructed based on information current as of 8 May 2020 and so material events that may have occurred since that time are not reflected.

1.2.1 Findings

1.2.1.1 Issues

Listing criteria observations

There are specific examples on the PL that can be considered as not meeting the criteria for listing. The most notable examples are topical skin adhesives and infusion pumps, which are not implanted (Criterion 4a) nor necessarily need to relate to an implantable device (Criteria 4b and 4c).

In addition, there has been an expansion in the nature of items being included on the PL. Even though these items generally meet the criteria, the inclusion of some is potentially at odds with the purpose of the PL. For example, while haemostatic devices are specifically designed to modulate a physiological process by way of stopping bleeding or the leakage of fluid, many of them are designed to dissolve and disappear a short while after their application or insertion. There is legitimate

concern as to whether these devices are truly "surgically implanted" or in line with the intention purpose of the PL, but the listing criteria is not clear on this point.

Usage observations

The 'High' priority GM items experienced high growth in aggregate. The analysis identified 12 groups of primary interest with either high total benefits paid or high growth (or both). For simplicity here, the top 3 groups that contributed towards total benefits paid (Table 1) and the growth in total benefits paid (Table 2) are shown below.

Table 1 – Total benefits paid[1] for GM items on the PL in FY19

Product Group	**Total benefits FY19** ($m)	**Proportion of total GM benefits FY19** ($m)
03.08.04 - Staples & Tackers	95.9	37.5%
03.08.02 - Internal Adhesives	43.0	16.8%
03.05.05 - Matrix	30.3	11.9%
All other GM groups	86.4	33.8%
Total GM category	**255.6**	**100.0%**

Table 2 – Growth in total benefits paid[2] for GM items on the PL from FY14 to FY19

Product Group	**Total PL benefits FY14** ($m)	**Total PL benefits FY19** ($m)	**Compound Annual Growth Rate (CAGR)**	**Proportion of growth in GM benefits** (%)
03.08.04 - Staples & Tackers	56.9	95.9	11.0%	43.4%
03.08.02 - Internal Adhesives	12.4	43.0	28.1%	33.9%
03.05.05 - Matrix	14.8	30.3	15.4%	17.2%
All other GM groups	81.5	86.4	1.2%	5.4%
Total GM category	**165.6**	**255.6**	**9.1%**	**100%**

The same three groups were responsible for over 65% of total benefits paid and nearly 95% of the growth in the GM category since FY14. At an item level, there were ten items which were responsible for 70% of the growth observed.

In addition to high raw usage, the following was 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.

[1] From the HCP1 dataset, which is 90% complete for FY19 – see Section 3.2.2

[2] From the HCP1 dataset, which is 90% complete for FY19 – see Section 3.2.2

- 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.

- 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.

Benefit amount observations

There was clear evidence of significant increases in benefit amounts for items in long-standing use that have not changed. In each case, usage increased following the increase in benefit amount.

In addition, there were several cases where the pricing relativities between products appeared at odds with differences in their clinical functionality. Again, usage was often skewed towards the more expensive versions.

Examples where these issues occurred include within Internal Adhesives - adhesive accessories and adhesives ≤2ml (03.08.02), Infusion Pumps, Balloon Based (03.02.02.01), and Pliable Patches (03.05.04).

Overall, the benchmarking analysis against the prices paid by public hospitals in two Australian jurisdictions did not suggest that GM items on the PL had significantly higher benefit prices than in the public system. However, this was partly circular for these items as the public system looked to the PL for a benchmark. Where the public system could achieve lower prices than the PL, this was usually a result of a tendering process and volume-based discounts, which the PL does not allow.

1.2.1.2 Causes

PL as a funding mechanism

There is a clear separation between the guaranteed funder of GM items (insurers), the chooser of the items (clinicians) and the provider of the items (private hospitals). This separation means that the value of the items is not a direct consideration when selecting which (and how many) GM items should be used in a procedure – i.e. there is no disincentive to the clinician to use more items of higher cost, even if the clinical benefit of doing so is negligible. Conversely, manufacturers and private hospitals operate in a commercial market and have more of an incentive to maximise use of devices that are available through the PL.

Whilst this can be argued for all items on the PL, it is particularly true for GM items because:

- They are available at a range of price points (due to, for example, varying sizes or additional features);

- They are often of low cost and so the marginal impact of additional use is minimal; and/or

- Multiple quantities of the item can be used in a single procedure and so there is no natural upper limit to how many could be used (as opposed to, say, a prosthetic hip).

Listing processes

There is a lack of rigour and robustness in the processes which surround: assessing items for inclusion on the PL; changing classifications (and benefit amounts) once an item is on the PL; and monitoring and enforcing appropriate levels of usage of items on the PL.

Listing criteria

There are some grey areas around the boundary for inclusion under criterion 4a. Specific issues arise from:

- The lack of a clear definition for a 'prosthetic' item;
- Ambiguity in the term 'implantable' – in particular, whether this should be long-term/permanent; and
- Ambiguity in the terms 'pathological process' and 'physiological process' – for example, whether these include processes such as bleeding which can result from the surgery itself but are not the main reason for the surgery in the first place.

Similarly, criteria 4b and 4c are open to interpretation since they do not require an explicit link to implantable devices to be specified, nor the extent to which it aids or continues to be critical to the implantable device.

1.2.2 Next steps

The recommendations below focus on directly addressing these issues.

Recommendation 1: remove the 'High' priority GM items from the PL

The following groups of items should be transitioned away from the PL and instead funded through case based or bundled fee arrangements:

- 03.02 Drug Delivery Devices;
- 03.05 Haemostatic Devices;
- 03.08 Closure Devices, specifically:
    - 03.08.01 Adhesion Barriers;
    - 03.08.02 Internal Adhesives;
    - 03.08.03 Ligating Devices;
    - 03.08.04 Staples & Tackers;
    - 03.08.05 Polypropylene/Polyester Mesh; and
    - 03.08.11 Dynamic Wound Closure Devices.

There is no suggestion that any of these items do not serve a clinical purpose in supporting improved patient health outcomes. As such, the transition considerations discussed below should be given due attention in order to avoid unintended consequences.

The main alternative to funding these items through the PL would be for them to be included within case based or bundled payments, such as DRG based payments or banded theatre fees relating to the nature of the procedure being performed under the National Procedure Banding schedule. The precise mechanism by which insurers reimburse these fees would depend on the arrangements

between insurers and hospitals. Clearly, the specifications and associated prices relating to the case based or bundled fees would need to be reviewed and updated to reflect their increased scope.

Theatre fees are intended to include consumables and disposable instruments. Including these items within such a group of costs and setting an overall single price for the group of costs that is related to the overall procedure is conceptually similar to Activity-based Funding (ABF) for public hospital services, except that it is at the scale of the operation.

The efficiency benefits that ABF enables in the public hospital setting are well documented and arise because of the resulting cost-risk sharing between the hospitals, clinicians and funders. The Independent Hospital Pricing Authority (IHPA) has found that ABF "provides a powerful incentive for hospitals to perform as efficiently as possible"[3] and has been successfully driving improved efficiency by transitioning towards ABF for public hospitals. This was based on earlier findings of the National Health and Hospitals Reform Commission (NHHRC) relating to both public and private hospitals, which recommended "the use of 'activity-based funding' for both public and private hospitals using case mix classifications".[4]

In the private hospital setting, there are similar case mix funding arrangements between hospitals and insurers. However, it is important to acknowledge that, in this setting, the cost-risk sharing dynamics are less immediate because the hospitals have limited control over clinicians' choices in the operating theatre, and hospitals and clinicians do not have the same financial incentives driven by a shared profit bottom line. For efficiency benefits to be realised, hospitals would need to engage proactively with their clinicians regarding procurement and usage of the items.

In addition to incentivising efficiency, these cost-risk sharing arrangements can also mean a reduced administrative burden for hospitals as it enables the review of a group of fees in aggregate rather than needing to reassess regularly the individual price points for all of the constituent costs.

Since most, if not all, of the items in this review can be considered disposable and/or consumable, it would be more consistent for these items to be included in case based or bundled payments with other disposable and consumable items.

This approach would also be consistent with the way other private funders such as Workers Compensation schemes, Compulsory Third Party insurers and the Department of Veteran Affairs treat consumable and disposable items which are typically included within case based payments or bundled theatre fees, with additional fees for high cost items only in exceptional circumstances.[5]

For the lower cost items where a range of alternative products might be able to perform similar clinical roles, the change in funding mechanism should not impact the volume and range of items stocked by hospitals and should therefore have limited impact on clinicians' choices. As some of these items have been previously funded in this way, it is clearly a feasible option.

Recommendation 2: tighten listing criteria

Amend the listing criteria in the Prostheses List Guidelines to include an overall intention for the PL and to remove any ambiguities.

[3] Activity based funding for Australian public hospitals: Towards a pricing framework (Independent Hospital Pricing Authority, 21 December 2011)

[4] A healthier future for all Australians (National Health and Hospitals Reform Commission, June 2009)

[5] https://www.sira.nsw.gov.au/__data/assets/pdf_file/0019/613009/Private-Hospital-Maximum-Rates-Order-2020.pdf

As well as being the means to achieve Recommendation 1, this will limit the potential for future 'creep' in the nature of the items included on the PL. By including an overall intention for the PL, it will be more apparent when items on the PL are inconsistent with this intention. This should describe how the PL is intended to enable patients to have access to safe, clinically effective and cost effective prosthetic items through guaranteeing appropriate funding levels towards those prosthetic items that are critical and specific to meeting certain patients' needs – with these latter circumstances expanded on depending on the Department's views.

In addition, including further details and definitions to clarify the specific ambiguity issues described above will enable a more objective assessment of an item's eligibility (or otherwise) for inclusion.

Recommendation 3: improve listing processes

Improve robustness of listing processes, including: assessments for inclusion; assessments for reclassification; monitoring of appropriateness of usage; and regular assessments of clinical value.

Ideally the assessment processes for inclusion and reclassification on the list would include a comprehensive assessment that considers:

- Whether it meets the (more objective) listing criteria;
- Transparent tendering processes – i.e. opening up the process so that other manufacturers can simultaneously propose benefit amounts for their own similar products;
- The clinical value of the product relative to its proposed benefit amount and the benefit amounts of similar products (including other products included in the tendering process as noted above, and also other products that are on the PL and not on the PL); and
- Whether more efficient funding mechanisms might exist.

Ideally these assessments would be performed by an independent panel comprising members with a range of clinical and health economics backgrounds.

Regular and formal monitoring of usage and compliance with the criteria should also be performed and reported to the panel. The panel should also have a framework in place for reviewing and assessing the clinical value of items on the PL.

Transition considerations

As noted above, there is no suggestion that any of these items do not serve a clinical purpose in providing for optimal patient outcomes, even though there are indications that some usage may be beyond what is clinically required. As such, it would be an adverse outcome if removal from the PL led to an increased cost burden for clinically essential items and/or a reduction in usage to the extent that clinical outcomes for patients were compromised.

A range of implementation issues should be considered in order to avoid unintended consequences from the removal of any items.

Most importantly, the processes and contractual mechanisms for including these items within case based or bundled payments will need to be developed and tested so that there are no short-term adverse impacts on clinical outcomes and the cost of services. In particular, hospitals and clinicians will need to properly develop, test and implement procurement and usage monitoring processes

and, given the clinical importance and volume of usage of these items, appropriate transition time should be allowed for this.

Other transitional arrangements to consider include for existing contractual arrangements and other agreements to expire and for new arrangements to be agreed.

1.2.3 Reliances and limitations

EY have relied on the data provided by the Department, by public hospital organisations from two Australian jurisdictions, as well as stakeholder feedback and other publicly available information. EY has not sought to verify the accuracy of the data, third party reports, or the information and explanations provided by the Department, nor does EY make any representations as to the reliability or completeness of the information provided. Any data limitations realised in the review process have been identified and highlighted in this report.

As requested by the Department, EY has taken a prioritised approach in the review of the items on the list, meaning that not all items in the GM category have been reviewed. As such, our analysis and findings have focused on the 'High' priority items that the Department identified are primarily responsible for usage and changes in usage across the GM category, as well as cases where significant changes in usage or benefit amount have been observed. The analysis and findings should not be interpreted as reflecting the experience of all items in the GM category.

Additionally, EY and the Department were not able to perform the entire consultation process with external stakeholders that was initially envisioned. As such, it is possible that there are specific circumstances that are not immediately apparent in the data that may go some way to explaining some of the observations made in this review. However, given the range of different interests of different stakeholder groups (see, for example, Section 2.4) and the strength and breadth of observations made, it is not clear if there are many objective explanations that materially alter the conclusions.

Additional detail on limitations to the approach can be found in Section 3.3, with further reliances and limitations described in Section 6.2.2.

2. Background and context

2.1 Prostheses List overview

The Prostheses List (PL) is a legislated list of prosthetic items and associated benefit amounts. It requires private health insurers to pay for prostheses that are provided to a privately insured person as part of an episode of hospital treatment. In doing so, it guarantees that private health insurers (insurers) will pay hospitals a set amount for every item used, with the intention of ensuring that patients have access to safe, clinically effective and cost effective prosthetic items.

There are around 11,000 items on the PL, representing the diverse nature of prosthetic items available to clinicians. These are separated into 13 'categories', one of which is the '03 – General Miscellaneous' (GM) category.

The GM category includes a wide range of surgical items which can be grouped into two broad types:

- Prosthetic items that are designed for a specific purpose which is central to certain types of surgical procedure, but that do not fit neatly into the other 12 categories of the PL. Brachytherapy and gastric band devices are examples of these '**miscellaneous**' items.
- Other medical items which are used to support a range of different types of surgical procedure which are either inserted into the body or assist other items that are inserted into the body. Drug delivery devices, haemostatic devices and closure devices are examples of these '**general**' items.

2.2 Challenges in the General Miscellaneous category

The current PL arrangement were established to control significant increases in the benefits paid for prostheses. In the early 2000s, the Department observed that while the number of private hospital services involving prostheses was decreasing, there was a significant increase in underlying prostheses cost and benefits paid.

This inflation in prostheses expenditure contributed to increases in premium costs, making private health insurance less affordable for Australian citizens. In response, the Department has introduced reforms aimed at moderating the rate of increase and controlling private health expenditure through legislative arrangements. The legislation, in the form of the PL, took effect in October 2005.

In 2017, Health Minister Greg Hunt reached an agreement with medical device manufacturers to bring down the costs of their products.[6] This was at least in part in response to complaints that prices on the list were significantly higher than what was being paid in the public sector and in comparable countries. However, with usage continuing to increase, there is some debate whether the intended savings have been delivered.

The GM category of the PL saw significant increases in utilisation and total benefits paid each year over the period from FY14 through to FY19. In this period, there was an 11% compound annual growth rate (CAGR) in the number of items used per year and a 9% CAGR in the total benefits paid over the period. More recently, from FY18 to FY19 the growth in utilisation of items in the GM category was 15%, although the corresponding growth in total benefits paid was lower, at 3%. The

[6] https://www.mtaa.org.au/sites/default/files/uploaded-content/field_f_content_file/affordability_of_medical_devices_agreement_between_government_and_mtaa.pdf

lower average benefit amount paid per item was partly due to benefit amount reductions and partly from high usage for new items on the PL with lower benefit amounts.

2.3 Basis for this review of the General Miscellaneous category

The concern which is the basis for this review is that using PL as a funding mechanism (which guarantees that insurers will pay a set amount for every item used) for low cost high usage items may not send a direct price signal to hospitals, and so:

- Usage of the item over and above the minimum level necessary to ensure patient outcomes is not disincentivised; and/or
- There may be higher than necessary usage of more expensive versions of equivalent products, including when they provide little/no clinical benefit over cheaper alternatives.

As a result, the Department has requested that this review focus on 19 'High' priority GM groups that are 'general use' items.

The following figures show the total number of PL items used and total PL benefits paid for the GM category from FY14 to FY19, split by the contribution from the 19 'High' priority groups and the remaining 'Low' priority groups.

Figure 3 – GM – Total Prosthetic Items

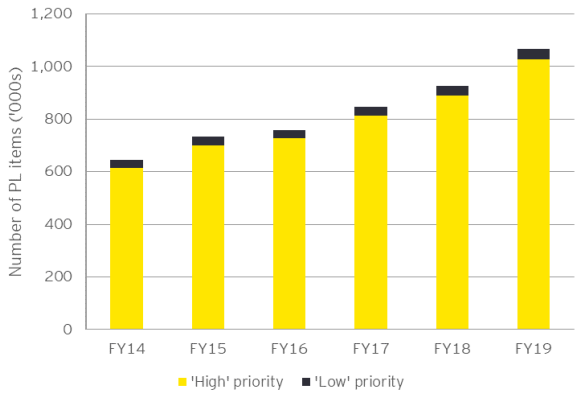
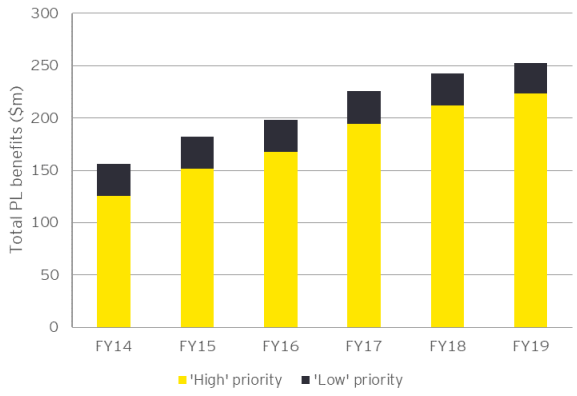


Figure 4 – GM – Total Prostheses Benefits



To address some of the issues regarding low-value, high-volume items on the PL, the Department of Health resolved to undertake a review of the GM category of the PL to determine whether items in that category (or a subset of items) should continue to be listed on the PL. This particular review also considers whether the cost of these devices is appropriate and whether suppliers are appropriately bundling items together.

2.4 Feedback from industry

Following the announcement of the GM review, and during the development of the Terms of Reference for the review, the Department received a variety of feedback from representative peak bodies and constituents in the private health insurance, medical device manufacturing, and private hospital industries.

The following sections summarise the feedback received prior to the review being undertaken.

2.4.1 Private health insurers

Overall, private health insurers in Australia were supportive of the review, due to pricing discrepancies between the prices paid in the public and private sectors, and their perception of over-utilisation and excessive benefit levels for low-cost items, which is damaging the affordability of private health insurance in Australia. Industry constituents conveyed a view that the current reimbursement mechanisms has led to perverse incentives for device manufacturers (such as exploitation of the list through combining products into a single item on the PL), and an overall failure in the market.

Private health insurers contended that the existence or current use of a product should not guarantee its funding through the PL, and that devices should be able to demonstrate clinical and cost effectiveness worthy of their listed price. In addition, other funding mechanisms do exist which have previously funded items that are currently on the PL and continue to fund comparable items. Many endorsed a transparent, data-driven and evidence-based approach to value-based policy reform, as their view was that many parties with vested financial interests may be less willing to engage in the substance of the reform.

2.4.2 Medical device manufacturers

Many medical device manufacturers were unsupportive of the review. Generally, they believed that the anticipated savings under the 2017 Agreement with the Medical Technology Association of Australia (MTAA) are being achieved. Where private health insurance industry and other research have suggested that savings are not being appropriately realised, some manufacturers claim that this was based on incorrect assertions and inaccurate data. They were concerned that removing items from the PL would constitute a breach by the Department of the Agreement and would have significant consequences for the private health system.

Some industry constituents criticised private health insurers for seeking to reduce benefit payments to improve their own profit. Furthermore, they voiced concern that the review of the GM category may set a precedent for reviews or adjustments to the listing criteria of other categories on the PL. They believed that doing so would represent a disservice to the PL mechanism, which provides no gap payments and certainty of access to innovative products for privately insured Australian citizens.

2.4.3 Private hospitals

Australian private hospitals were generally supportive of a careful, considered and evidence-based reform to the PL, but were very concerned that this review may involve arbitrary cuts to the items on the PL based on pricing. Some were concerned that the removal of items would be detrimental to the provision of hospital services that could even threaten the closure of some hospitals.

Furthermore, some hospitals suggested that such removal could limit surgeon choice or compromise clinical outcomes for patients. In feedback to the Department, it was highlighted that private hospitals would be required to absorb the cost of items not covered by the benefits on the PL or pass costs onto patients through increased benefit outlays.

3. Scope and Approach

3.1 Scope and purpose of the review

The scope for this project was to review the GM category of the PL. Details on the PL and the GM category are included in Sections 2.1 and 2.2.

The report presents evidence and commentary on specific items within the GM category of the PL and provides considerations around whether their inclusion on the PL appropriate. The Terms of Reference for the review were to:

1. Consider whether items listed in the GM category meet the current criteria for listing of prostheses on the PL as set out in legislation and guidance documents;

2. Examine Hospital Casemix data to identify trends in use and expenditure in the GM Category;

3. Consider whether items listed in the GM category are also funded through other private health insurance payments;

4. Consider whether for reasons of improved efficiency, items in the GM category should be removed from the PL and funded by private health insurers through other mechanisms;

5. Consider whether there would be unintended consequences should any items in the GM category be removed from the PL; and

6. Consider whether any items listed in the GM category should undergo a health technology assessment to determine their comparative value.

It was determined by the Department that the review would consider all products within the GM category, but that the priority focus would be placed on the 'general use' product groups as opposed to the 'Miscellaneous' items (see Section 2.1 for definitions of these terms). This would enable a more targeted review that could have a greater impact in addressing the issues with high-volume, low-value items on the PL.

Although the review was confined to the GM category, there are other 'general use' items that sit in other categories of the PL, and hence the outcomes of the review may also have implication for those items.

The review sought to contribute towards the Department's strategic review and delineation of the overall purpose for the PL. This broader piece of work attempts to align many of the activities being undertaken by the Department in this key time of its PL reform actions to support sector stability, sustainability, safety, transparency and innovation.

3.2 Approach

The approach to this review covered six sequential phases:

1. **Kick-off:** an initial two-week mobilisation period, which included a planning workshop with key Departmental personnel to inform the overall project charter and stakeholder engagement plan;

2. **Initial stakeholder consultation:** a Department-led stakeholder consultation process which was facilitated through a PHI circular. This was in addition to the preliminary feedback described in Section 2.4;

3. **HCP data analysis:** identification and analysis of trends in benefit amounts and usage, including analysis into usage with other items on the PL, the medical procedures for which items were being used and variations of usage between hospital owners;

4. **Benchmarking:** utilisation of benchmarking data to undertake a pricing comparison between the PL and the public hospital system in two Australian jurisdictions;

5. **Inputs from clinical subject matter resources:** a review of the current state including clinical usage, funding methods, impact of listing and benefit amounts from EY's subject matter resources; and

6. **Review and reporting:** review of the draft report by the Department prior to finalisation of the report.

Due to the onset and disruption caused by COVID-19 to the Australian Healthcare industry, it was not possible for later rounds of consultation to be run as had been the initial intention.

3.2.1 Structure of analysis

The analysis and findings have been grouped in the report based on the following potential key types of issues:

1. Issues with the listing criteria and categorisation approach – Section 4.3. This component is intended to address the Terms of Reference item 1.

2. Issues relating to high and/or highly growing usage – Section 4.4. This component is intended to address the Terms of Reference item 2.

3. Issues relating to benefit amounts – Section 4.5.

Further details on the investigation approach is included at the start of each of these sections.

In Section 4.6, it is considered whether alternative (non-PL) funding mechanisms are available for the same items analysed in Sections 4.4 and 4.5, and whether the use of these mechanisms might have the potential to reduce overall costs. This component is intended to address the Terms of Reference items 3.

Section 5 then highlights key case studies where products on the PL have potential issues across more than one of these areas.

Section 6 provides a summary of the findings with recommendations for improvement that the Department should consider. This component is intended to address the Terms of Reference items 4 and 5.

3.2.2 Data

3.2.2.1 Hospital Casemix Protocol data

The HCP1 dataset was used to provide information on the benefits paid and total usage of items on the PL, as well as information related to the associated episodes of care. This dataset includes episode-level data on the items charged to private health insurers that were from the PL, the amount charged, the benefit paid, and other demographic information relating to the episode.

The completeness of the HCP1 data was assessed by comparison to APRA's private health insurance statistic figures for prostheses usage. APRA's statistics represent a complete picture of all payments by insurers for PL items at an aggregated level.

Specifically, the total number of prosthetic items used was compared between the HCP1 and APRA datasets to provide a completeness percentage for private and day hospitals and public hospitals, separately. The average prostheses benefit amount paid in each year was also compared to give an indication of the representativeness of the HCP1 dataset.

Completeness of the data

Table 3 summarises the results of this comparison between the HCP1 and APRA datasets. The HCP1 prostheses dataset was deemed close to 'complete' for private and day hospitals, with 91% overall completeness over the period from FY11 through FY19.

It is noted that completeness for private prostheses usage in public hospitals was significantly lower than private hospitals, with 49% overall completeness for the same period. Usage of prostheses in public hospitals but funded through the PL, however, represented a relatively small proportion of total PL-funded prostheses usage - approximately 10% based on the APRA-reported figures. The overall 'completeness' of the HCP1 dataset across all hospitals was 87% for FY11 – FY19.

The impact of the small proportion of incomplete HCP1 data on the average prostheses benefit paid was minimal, with the average PL benefit amount from HCP1 being within approximately 1% or less of the APRA-reported amounts.

Table 3 – Comparison of HCP1 and APRA prostheses data

Financial Year	Completeness of number of prosthetic items used (HCP1 vs APRA)			Average Prostheses Benefit Paid (All hospitals)	
	Private and day hospitals	Public hospitals (Private treatment)	All hospitals	HCP1	APRA
FY11	83%	57%	81%	$785	$784
FY12	85%	60%	83%	$773	$771
FY13	92%	52%	88%	$774	$765
FY14	87%	47%	83%	$774	$765
FY15	93%	47%	88%	$773	$776
FY16	92%	48%	87%	$788	$789
FY17	94%	48%	89%	$776	$775
FY18	94%	47%	89%	$727	$733
FY19	95%	46%	90%	$665	$670
FY11 – FY19	**91%**	**49%**	**87%**	**$754**	**$755**

Allocation of PL benefits across other associated PL categories

Part of the analysis performed using the HCP1 dataset involved assessing the extent to which usage of the GM items deemed as 'High' priority by the Department (prioritisation discussed below in Section 4) was associated with usage of other PL items outside of this 'High' priority GM category within the same episode of care. The purpose of this analysis was to confirm which criteria for listing were relevant to the item.

To perform this analysis, the amount of PL benefits associated with these 'High' priority GM items were allocated between each of the other categories of the PL (including the 'Low' priority GM items) using the following process:

1. For each episode of care associated with usage of 'High' priority GM items, the total PL benefits in respect of each non-GM category and 'Low' priority GM items within the same episode of care was summarised.

2. For each instance of usage of 'High' priority GM items, the total PL benefits for that usage was then allocated between each of these categories (including 'Low' priority GM) in proportion to the relative benefits paid in respect of each of these categories within the same episode of care (as calculated in Step 1).

3. If an instance of usage of 'High' priority GM items was not associated with any PL items outside of this 'High' priority GM grouping, then the full PL benefit amount was allocated to the 'None' category.

Primary MBS item code

Further analysis was performed using the HCP1 dataset to investigate usage and benefits for GM items by the primary MBS item code for the associated episode of care. Each episode of care may be associated with multiple MBS item codes. For this analysis, only the 'primary' MBS item code was considered. The 'primary' or 'principal' MBS item code was used as implemented within the HCP1 dataset[7]. This is defined within the HCP1 data specifications as being selected "on the basis of: (a) the patient's first visit to a theatre or procedure room/coronary angiography suite; and (b) the MBS with the highest benefit amount".

Usage comparisons between private hospitals

The HCP1 data includes information on the hospital where the procedure was performed, which has also been analysed. However, in this analysis, focus was placed on the hospitals' owner groups rather than individual hospitals themselves. Analysis of individual hospitals could be helpful to investigate how contracting differences and clinical preferences may be influencing usage of these GM items. Due to the large number of items and hospitals, this would have been a significantly large analysis and not feasible given the constraints of this review.

3.2.2.2 Benchmarking data

To augment the data analysis and supplement key market and clinical consumption insights across Australia, robust benchmarking data was leveraged from the Australian public health sector for a clear and direct comparison across the market. Data for the benchmarking exercise was compiled from the pricing schedules for two Australian state public health systems. To ensure data comparability, products were benchmarked at the same unit of measure as they appeared on the PL.

The purpose of the benchmarking exercise was to compare public and private prices to determine whether the products in scope are listed on the PL at above, below or at average market price in the public domain.

Given that the data was compiled from EY's recent work in prostheses procurement, the source of the data confirmed accuracy and reliability of the information. With respect to the completeness and relevance of the benchmarking, the pricing information available was able to enrich the data

[7] See https://www1.health.gov.au/internet/main/publishing.nsf/Content/health-casemix-data-collections-about-HCP

analysis of a significant portion of products within the GM category, which were matched to the PL through the product's Billing Code, Australian Register of Therapeutic Goods (ARTG) number, or brand name and description, and then reconciled to an 'each' unit of measure for comparability to the PL benefit amounts.

3.2.3 Stakeholder consultation

A summary of feedback received by the Department prior to the review (in the development of the Terms of Reference for the review) is given in Section 2.4. During the review itself, additional feedback was sourced through direct stakeholder engagement conducted by the Department.

Private health insurers, hospitals and other registered parties were reminded of the review via a PHI Circular, and there was a call for submissions through the Department's Consultation Hub. The Department contacted specific organisations (including those organisations who provided feedback on the Terms of Reference) via letter and email to update them in line with the PHI Circular and invite responses or submissions against questions via the Consultation Hub. Feedback from these groups was aimed at understanding which items meet criteria for listing, and whether items are, or could be, funded through alternative means.

Clinical subject matter resources also participated in workshops to discuss listing criteria, product usage, alternative treatment options and preliminary findings. Feedback received from stakeholders was integrated with desktop and data findings to develop a more holistic view of the current state.

It was intended that the Department would conduct further rounds of consultation in which feedback would be received on the preliminary findings from the data analysis and benchmarking, and on selected observations in the context of the six items in the Terms of Reference. However, the onset and impact of COVID-19 on the Australian Healthcare Industry meant that it was not possible for these additional rounds of consultation to be held.

3.3 Limitations

The limitations associated with the review include the reliance on data provided by the Department and public hospitals, the prioritisation approach taken to complete the review, and a shortened consultation process due to COVID-19. These limitations are discussed in the sections below.

3.3.1 Data

Reliance was placed upon the HCP1 dataset provided by the Department to perform analysis relating to the usage and benefits paid for various items and groupings on the PL. As described above, this data was checked for completeness by comparing the total number of PL items used in both the HCP1 dataset and the (complete) APRA-reported private health insurance statistic figures. Additionally, the average prostheses benefit amount paid was compared between both these datasets in order to verify whether the HCP1 subset of the complete data was representative. The results of these checks can be found in Section 3.2.2.1.

Analysis was conducted linking usage of 'High' priority GM items with other PL items outside of the 'High' priority GM category within the same episode of care. This analysis required apportionment of PL benefits for 'High' priority GM item usage between the different PL categories (and 'Low' priority GM) to assess the extent of benefits where 'High' priority GM usage related to these other categories. This analysis was therefore dependant on the apportionment process used. For the purposes of this review, these benefits were apportioned between each other PL category (and 'Low' priority GM) in proportion to total benefits paid for each within the same episode of care.

Analysis of the MBS item associated with the use of a PL item was based on the 'primary' MBS item code for the associated episode of care; the definition of the 'primary' or 'principal' MBS item code is explained in Section 3.2.2.1. However, episodes of care can be associated with multiple MBS items, and this information is retained in the HCP1 dataset. The analysis performed did not use any MBS item codes other than the primary MBS item code, which reduced the granularity of the information and the associated procedures.

Limited publicly available data in relation to the use of PL items in the public sector meant that meaningful comparison of the usage of items between sectors was unable to be performed.

3.3.2 Prioritised approach

It was not necessary to analyse all GM items, given many make little contribution towards total benefits paid and/or were determined by the Department as being 'miscellaneous' items that were not the focus of this review.

In any case, it was not feasible to assess all aspects of usage for every item in the GM category of the PL due to the number of items and the number of potential variables (and multiples of variables) against which to compare usage.

As such, and as discussed in Section 4.1, groups in the GM category were prioritised into 'High' and 'Low' priority. Within the 'High' priority groups, investigations into the subgroups and suffix groups were prioritised based on factors such as their total contribution to PL benefits paid, the overall level of item usage, and the growth in both their benefits and item usage over time.

Further, the review focused on identifying key examples of the experience and behaviours which address the Terms of Reference for the review, as outlined in Section 3.1. Therefore, the findings in this report cannot be interpreted as applying across all items in the GM category.

3.3.3 Shortened consultation process

As noted in Section 3.2.3, the Department originally intended to conduct additional stakeholder consultations on selected observations. It is possible that there were specific circumstances that are not immediately apparent in the data that may go some way to explaining some of the observations made in this review. However, given the wide range of views expressed by the different stakeholder groups (see, for example, Section 2.4), it is unlikely that these would materially alter the conclusions.

4. Review of GM items

Items in the GM category of the PL were reviewed and assessed in line with the objectives outlined in this section, incorporating insights from a combination of the three main components of the review, specifically:

- Quantitative analysis of HCP1 prostheses usage and benefits data;
- Benchmarking analysis comparing prostheses benefit amounts between the private and public hospital systems in Australia; and
- Consultation with relevant stakeholders.

4.1 Prioritisation of groups

For the purposes of assessing the underlying factors and key areas driving the high-level growth in the GM category, an initial prioritisation lens was provided by the Department classifying each of the 43 component groups of the GM category (as at February 2020) as either 'Low' or 'High' priority for the review.

The full table of all 43 groups, including groups that were determined as low priority by the Department, is found in Appendix A.

This initial prioritisation lens was driven by the Department's initial internal analysis, which showed a change in utilisation or expenditure for some items or where there may be some debate around whether they should really be thought of as prosthetic items in their own right. The 'Low' priority subcategories/groups are therefore generally items that are clearly prosthetic in nature (but do not sit within other categories of the PL) or where initial analysis did not show any significant changes in utilisation.

The **'High'** priority subcategories/groups were:

- 03.02 Drug Delivery Devices
- 03.05 Haemostatic Devices
- 03.08 Closure Devices, specifically:
    - 03.08.01 Adhesion Barriers
    - 03.08.02 Internal Adhesives
    - 03.08.03 Ligating Devices
    - 03.08.04 Staples & Tackers
    - 03.08.05 Polypropylene/Polyester Mesh
    - 03.08.11 Dynamic Wound Closure Devices

The **'Low'** priority subcategories/groups were:

- 03.01 Brachytherapy
- 03.03 Enteral Tubes
- 03.04 Gastric Bands
- 03.06 Luminal Stents
- 03.07 Pulmonary/Peritoneal Devices
- 03.09 Bowel Incontinence Devices
- 03.08 Closure Devices, specifically:
    - 03.08.06 Composite Mesh
    - 03.08.07 Complete Biomaterial Mesh
    - 03.08.08 PTFE/ePTFE Mesh

- 03.08.09 Plugs
- 03.08.10 Anastomosis Clip

This was then overlaid with a risk-based prioritisation of each of the 'High' priority groups according to the total volume of benefits and levels of growth in these benefits over the period from FY14 through to FY19 both in absolute magnitude (i.e. dollar value growth) and in relative terms (i.e. percentage growth). Additionally, groups with low average benefit amounts but high levels of usage were flagged for further investigation. Of the 19 groups classified as 'High' priority by the Department, 12 were investigated further following this risk-based prioritisation.

Table 4 provides a summary of the outcomes of this prioritisation, showing only the 19 groups that were classed as 'High' priority by the Department, with the 12 groups that were included for further investigation highlighted. Each of the 19 groups initially prioritised by the Department are shown with the total amount of PL benefits paid with respect to each group for FY19. There were additional indicators for whether this group was deemed be 'EY High Priority' based on a combination of whether the group was a 'High benefits paid' group and/or a 'High growth' group (in respect of total benefits paid).

Table 4 – Summary of prioritisation of GM product groupings

Product Group	Total Benefits FY19 ($m)	EY High Priority	High item usage	High benefits paid^	High growth^
03.02.01 - Infusion Ports	0.3	×	×	×	✓
03.02.02 - Infusion Pumps, Balloon Based	5.8	✓	✓	✓	✓
03.02.03 - Infusion Pumps, Battery Powered (Part A)#	4.4	✓	×	✓	✓
03.02.04 - Infusion Pumps, Spring Powered	0.7	×	×	×	×
03.02.05 - Infusion Pump Accessories (Part A)#	1.0	✓	✓	~	✓
03.02.06 - Pharmaceutical Beads	0.1	×	×	×	×
03.05.01 - Occluder Pin	0.0	×	×	×	×
03.05.02 – Powder	0.7	✓	×	×	✓
03.05.03 – Sponges*	0.6	✓	✓	×	×
03.05.04 - Pliable Patches	3.0	✓	✓	✓	~
03.05.05 – Matrix	30.3	✓	✓	✓	✓
03.05.06 – Foam	2.1	✓	✓	✓	✓
03.08.01 - Adhesion Barriers	4.6	✓	×	✓	~
03.08.02 - Internal Adhesives	43.0	✓	✓	✓	✓
03.08.03 - Ligating Devices	27.3	✓	✓	✓	~
03.08.04 - Staples & Tackers	95.9	✓	✓	✓	✓
03.08.05 - Polypropylene/Polyester Mesh	3.7	×	×	✓	× Significant decreases
03.08.10 - Anastomosis Clip	0.0	×	×	×	×

Product Group	Total Benefits FY19 ($m)	EY High Priority	High item usage	High benefits paid^	High growth^
03.08.11 - Dynamic Wound Closure Devices	0.0	×	×	×	×

#Indicates groups which include products on both Part A and Part C of the PL

4.2 Summary of observations

Each of the 12 prioritised groups listed above were analysed in greater detail to identify specific observations relating to the key objectives of the review (as outlined in Section 3.1). For these groups, analysis was performed to investigate trends and observations at the group, subgroup, suffix and item level and overlaid with insights gathered from consultation with stakeholders and clinical input.

The investigations performed incorporated various areas of analysis, including:

- Analysis of the trends, relativities and relationships in usage levels, paid benefits and average benefits per item/minimum benefit amounts at the group, subgroup, suffix and item levels.
- Analysis of these trends, relativities and relationships across:
    - The 'primary' MBS codes associated with their usage; and
    - The main hospital owners / groups associated with their usage.
- Analysis of the association in the same episode of care between usage of these items and usage from other PL categories or with GM items flagged as 'Low' priority by the Department. The purpose of this analysis was to confirm which criteria for listing were relevant to the item.

Observations arising from this review were made across several main areas, specifically:

- **Alignment of items with the listing criteria:** this relates to whether the item/s themselves should be on the PL, given the criteria specified by the Department for listing on the PL. More information on the listing criteria is found in Section 4.3.1, with specific examples in Section 4.3.2.
- **High levels of usage or above trend growth in usage:** this relates to where item/s were being used at high levels compared to other item/s in the same grouping, or where the growth in usage of item/s differed significantly to the growth in usage of other item/s in the same grouping. Examples of these are found in Sections 4.4.2, 0 and 4.4.4.
- **Significant increases in benefits per item:** this relates to where there was a significant increase in the average amount of benefits paid for each item in a grouping for a financial year compared to previous financial years. See Sections 4.5.1 and 4.5.2 for discussion of this analysis.
- **Anomalies in the relativities between benefit amounts:** this refers to where groups, subgroups, suffixes or items appear to be similar in nature, but are listed in different sections of the PL and thus have different minimum benefit amounts, potentially impacting their usage and/or the total PL benefits paid for the items. Examples of this are found in Section 4.5.3.

- **Issues in the categorisation of items:** this relates to where the reclassification of GM items from one subgroup or suffix into another subgroup or suffix caused a significant increase in the minimum benefit amount payable for these items, without any apparent change to the underlying product. Examples of this are found in Section 4.5.2.

- **Availability of alternative funding mechanisms:** this introduces the main alternative funding mechanism would could be applied instead of the PL to any of these items. See Section 4.6 for a discussion of the main alternative funding mechanism, with further discussion on its merits in Section 6.2.1.

- **Price benchmarking between private and public hospitals:** this relates to observations made when comparing prices for an item listed on the PL and the same item as purchased by two different public health systems. See Section 4.5.4 for discussion of this benchmarking.

Table 5 summarises where such observations were made across each of these areas for the primary subgroups of each of the 12 prioritised GM groups. In this table, areas where significant issues or concerns were noted are coloured in red and areas where some minor issues or concern were noted are coloured in amber, while areas coloured in yellow had minor concerns noted but not discussed in detail in this report. Subgroups which were not investigated in detail due to having total benefit amounts that were not deemed to be material have been excluded from this table. The key findings from this analysis across each of the above areas of observations are discussed in the following subsections and in the relevant case studies in Section 5.

Table 5 – Summary of observations made across product subgroups

Product Subgroup	Alignment with listing criteria	Above trend usage	Significant benefits per item increases	Benefit amount relativity anomalies	Categorisation issues	Alternative funding mechanisms available	Price benchmarking
03.02 – Drug Delivery Devices							
03.02.02 – Infusion Pumps, Balloon Based							
03.02.03 – Infusion Pumps, Battery Powered							
03.02.05 – Infusion Pump Accessories							
03.05 – Haemostatic Devices							
03.05.02 - Powder							
03.05.03 – Sponges							
03.05.04 – Pliable Patches							
03.05.05 - Matrix							
03.05.06 - Foam							
03.08 – Closure Devices							
03.08.01 – Adhesion Barriers							
03.08.02 – Internal Adhesives							
03.08.03 – Ligating Devices							
03.08.04 – Staples and Tackers							

4.3 Listing criteria and categorisation

This section of the analysis considers whether items listed in the GM category meet the current criteria for listing of prostheses on the PL as set out in legislation and guidance documents.

In addition, it considers whether the listing criteria and categorisation approach themselves contribute to issues with the number and nature of items on the PL which, in turn, is leading to higher than necessary private healthcare costs.

The approach was to review relevant legislation and guidance, and to consult with clinical subject matter resources.

This component is intended to address the Terms of Reference item 1.

4.3.1 Outline of criteria

The criteria governing the listing of products on Part A of the PL are provided within the Prostheses List Guide published by the Department. These criteria are applied by the PLAC. Beyond the requirement that the 'prosthesis' be listed with approval of the Minister in the *Private Health Insurance (Prostheses) Rules* there is no overarching 'purpose' for the PL, no definition of the term 'prosthesis' and no description of what is intended to be covered by the PL within the *Private Health Insurance Act 2007.* Effectively, therefore, in the context of the PL a product is eligible to be deemed a 'prosthesis' if it satisfies those criteria as set out in the Prostheses List Guide.

The criteria for listing as provided in the Prostheses List Guide as at February 2017 are reproduced below:

Table 6 – Prostheses List Guide, February 2017, Revision 3 - Criteria for listing on Part A

	Criterion
1	The product must be entered and current on the Australian Register of Therapeutic Goods
2	The product must be provided to a person as part of an episode of hospital treatment or hospital-substitute treatment
3	A Medicare benefit must be payable in respect of the professional service associated with the provision of the product (or the provision of the product is associated with podiatric treatment by an accredited podiatrist)
4	A prosthesis should:
a	be surgically implanted in the patient and be purposely designed in order to
i	replace an anatomical body part; or
ii	combat a pathological process; or
iii	modulate a physiological process;
	or

b	be essential to and specifically designed as an integral single-use aid for implanting a product, described in (a) (i), (ii) or (iii) above, which is only suitable for use with the patient in whom that product is implanted
c	be critical to the continuing function of the surgically implanted product to achieve (i), (ii) or (iii) above and which is only suitable for use by the patient in whom that product is implanted
5	The product has been compared to alternative products on the PL or alternative treatments and
i	assessed as being, at least, of similar clinical effectiveness; and
ii	the cost of the product is relative to its clinical effectiveness

In short, to be deemed eligible for listing, in addition to legislative requirements pertaining to therapeutic goods and eligible private health insurance treatments, a product must either be:

- surgically implantable specifically for certain core purposes such as replacing an anatomical body part; or
- constitute an essential single-use aid for implantation of such a product; or
- be critical to the continuing function of such an implantable product.

It is further provided that any such product must be compared to alternatives on the PL and deemed to be of at least similar clinical effectiveness and having a cost relative to its clinical effectiveness.

The Prostheses List Guide provides some rationale for the inclusion of each of these criteria. In particular, it notes that for criterion 4(b) the requirement for a single-use aid to be "specifically designed" and "integral" precludes products of a more general nature, such as "sutures, scalpels, [and] trocars", which do not have a "unique and direct connection to the [implantable] product". Further clarification is provided that "single-use" means the product is "incapable of future use, and may only be discarded" and that it "does not have a general-purpose use".

Additionally, it is further clarified that for criterion 4 (c) the product must "not be a generic disposable or consumable item" and that items such as "batteries, catheters, cannula and similar accessories" without an ongoing association with the product are "considered to be disposable products" and hence do not meet criterion 4 (c).

It should be noted also that criterion 5 (ii) explicitly does not make reference to "cost-effectiveness", which is not considered as part of the assessment procedure for consideration of products for inclusion, as per the rationale provided in the Prostheses List Guide.

4.3.2 Alignment of criteria

As part of the review, products in the GM category of the PL were considered at a high level against the listing criteria outlined above to identify potential cases where groups of items may be considered to not fully align with these criteria. Instances where application of the current criteria and processes have potentially led to poor outcomes have also been considered.

For the purposes of the review, the Department identified several product subcategories or groups as being likely to constitute products of primary importance to the patient's treatment and are

therefore of lesser priority for the review, as outlined in Section 4.1. These were considered as being not of concern in regard to assessment against the listing criteria and, as such, whether these products align to the criteria has not been explicitly considered.

For those parts of the GM category which were deemed as 'High' priority by the Department, several instances where products may not fully align with the criteria, or where there are apparent inconsistencies in product classifications, have been identified on the basis of the more detailed analysis performed for these items and stakeholder consultation submissions. This section highlights key examples where potential issues have been identified but is not necessarily an exhaustive list. Opportunities for improvements based on these observations are provided in Section 6.

4.3.2.1 Potential issues with internal adhesives

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'.

The suggestion that these topical skin adhesive products are distinct from other products in the '03.08.02 – Internal Adhesives' group is supported by the fact that, following their introduction in February 2017, total benefits for the '03.08.02.01 - Adhesive ≤2ml' subgroup increased from $3.0m in FY17 to $18.6m in FY19: an increase of over $15.6m in a two year period. Further discussion of usage for this group is provided in the case study in Section 5.2.

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 criterion 4a. Therefore, argument for their inclusion must be based on either of criteria 4b or 4c.

The rationale for criterion 4b provided in the Prostheses List Guide, as discussed in Section 4.3.1, specifically indicates that items of "a more general nature (e.g. sutures, scalpels, trocars)" are not included because these would not fulfil the need for a product to be "specifically designed for implanting a product [that meets criterion 4a]". Based on stakeholder submissions and clinical input, it may be argued that these items are indeed of a general nature in that their use is not specific to the implantation of a prosthetic item, with parallels drawn to sutures which are similarly used for skin closure. There is therefore reason to question whether these topical skin adhesives meet criterion 4b. It also stands to reason that criterion 4c may also be considered insufficient for these products due to their temporary nature, which suggests that they cannot be considered as "critical to the **continuing** function of the surgically implanted product" (emphasis added). It follows then that there is significant room to question whether these topical skin adhesive products meet the PL listing criteria.

4.3.2.2 Potential issues with infusion pumps

Infusion pumps are designed to assist in the management of pain or to provide medication to a patient for relatively short periods that may be repeated over a longer period of time. Potential issues regarding the listing criteria were noted for these devices. It is clear that infusion pumps cannot themselves be considered surgically implanted due to their function external to the patient's body.

In that case, the surgically implanted device that their usage may be considered to relate to would necessarily be a portacath or long term vascular access line to which the pump is connected to enable delivery of the medication. Whether the pump is critical to the functioning of the portacath or access line, or vice versa, is debatable – especially as other mechanisms for administering medicine through the implanted device may be available.

Conversely, as shown in Appendix B (Figure 44 and Figure 45), infusion pumps are often used without another implantable device on the PL. This occurs around 50% of the time for balloon-based infusion pumps, 40% of the time for other pharmacology battery powered infusion pumps and 15% of the time for programmable/reprogrammable flow rate and bolus battery powered infusion pumps are "only suitable for use by the patient in whom that product (i.e. the portacath or long term vascular line) is implanted."

Further, there is a case that the infusion pump and port in tandem are purposely designed to modulate a physiological process or combat a pathological process in that they are designed to allow the delivery of medication to the patient, with the medication performing the modulating or combating role.

These arguments similarly extend to infusion pump accessories.

The case that infusion pumps meet the criteria for listing on the PL relies on the infusion pump and portacath working in tandem to modulate a physiological process or combat a pathological process. It ignores the issues above about whether each is critical to the functioning of the other, and also that it is technically the medication which is modulating or combating processes. Indeed, it was also suggested in consultation submissions that these devices do not represent 'true' prosthetic devices as they are primarily a method for the delivery of medication and do not remain well beyond discharge.

For some battery-powered infusion pumps there is further potential argument against their meeting of the listing criteria. It was suggested both by stakeholder consultation submissions and clinical subject matter resources that battery-powered pumps are capable of being reused for multiple patients and are not single use. If this is true, then these products appear to not meet with the listing criteria as both criteria 4b and 4c require the product to be "only suitable for use with the patient in whom that product is implanted". This is supported by that fact that some battery-powered infusion pumps included in Part A of the PL can cost as much as $4,950 per item as at February 2020.

Finding 4.3.2 (1)

There are specific examples on the PL that can be considered as not meeting the criteria for listing.

On the basis that topical skin adhesives are used externally and not necessarily in conjunction with other implanted devices (except potentially other 'High' priority GM items), the expectation is that these items do not meet the criteria. It is also noted that these items have previously been funded through case based or bundled fee arrangements between hospitals and insurers.

For a number of reasons outlined in Section 4.3.2.2 above, the case that infusion pumps meet the criteria for listing is tenuous at best. Given that pumps are regularly used without implantable devices and, conversely, that implantable devices (portacaths and long term vascular lines) can be used without pumps, the expectation is that these items do not meet the criteria.

4.3.2.3 Potential issues with haemostatic devices

Whilst it is clear that products included in the '03.05 – Haemostatic Devices' sub-category are specifically designed to modulate a physiological process by way of stopping bleeding or the leakage of fluid, many of them are designed to dissolve and disappear a short while after their application or insertion. In the current criteria there is no indication that duration is a factor in defining a product as being "surgically implanted". However, consultation submissions and clinical subject matter resources indicated concern as to the appropriateness of claiming such items as being truly "surgically implanted" or in line with the intention of the criteria or the PL more generally.

It is acknowledged that there is no overall purpose of the PL, which means that the broad interpretability of the current listing criteria results in a lack of clarity around what should and should not be considered a prosthesis. Further, in the case of these items, the process being modulated is that of bleeding or leakage often as a consequence of a surgical procedure (rather than modulating or combatting a process being the primary reason for the surgery in the first place) which may represent a broader effective coverage than originally intended.

4.3.2.4 Potential issues with staples and tackers

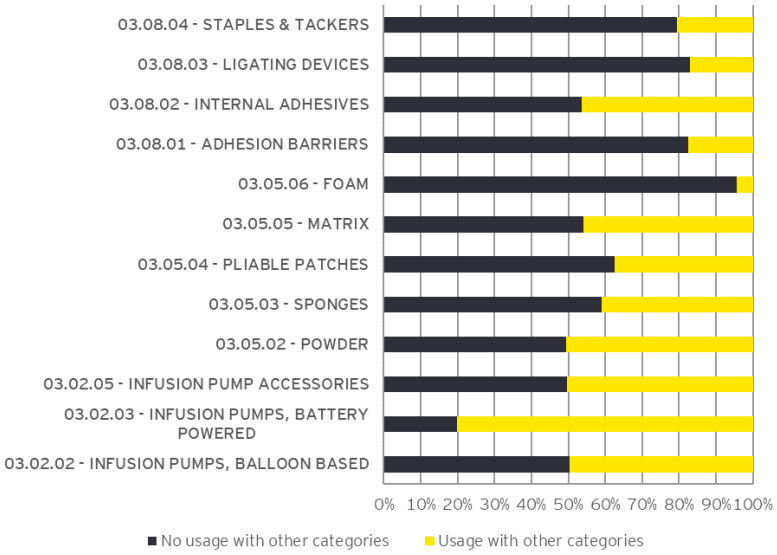
Similarly, it is clear that staple and tacker items from the '03.08.04 – Staples & Tackers' group represent clinically effective products that help to achieve wound closure, connect tissues and manage leakage of fluids. However, clinical subject matter resources also indicated that there is room for argument as to whether these items are considered 'prostheses' outside of the context of the specific listing criteria. Again, this is reflective of the broad interpretability of the listing criteria, particularly regarding the term "surgically implanted" and the wide range of purposes covered by criteria 4 (a) i – iii.

4.3.2.5 Usage of 'High' priority GM items with other prosthetic items

More generally, many of the 'High' priority GM items were infrequently used in the same episode of care as items from other parts of the PL (i.e. other PL categories or 'Low' priority GM items). In these circumstances, the item cannot be claimed to meet criteria 4b or 4c and so therefore can only be eligible if it meets criterion 4a.

In order to meet criterion 4a, the GM item is essentially the primary purpose prosthetic item in the procedure, which may be at odds with the intention of the PL. In particular, product groups such as '03.08.04 – Staples & Tackers', '03.08.03 – Ligating Devices' (except clips and clip appliers), '03.08.01 – Adhesion Barriers' and '03.05.06 – Foam' all showed greater than 80% of total benefits paid were not associated with any usage outside of the 'High' priority GM items. This is shown in Figure 5 below. It is noted that this does not necessarily indicate a lack of compliance with the listing criteria as stated, since these items can be argued to be implantable.

Figure 5 – 'High' priority GM – Proportion of usage with other categories



Finding 4.3.2 (2)

There has been an expansion in the nature of items being included on the PL. There is now a spectrum of items on the PL: from items that are clearly implanted prosthetic items through to items that are not strictly implanted themselves and/or are general use items that do not directly address the reason for surgery, and a range of items in between.

There are a number of grey areas around the boundary for inclusion under criterion 4a. Specific issues arise from:

- The lack of a clear definition for a 'prosthetic' item;
- Ambiguity in the term 'implantable' – in particular, whether this should be long-term/permanent; and
- Ambiguity in the terms 'pathological process' and 'physiological process' – for example, whether these include processes such as bleeding which can result from the surgery itself but are not the main reason for the surgery in the first place.

Similarly, criteria 4b and 4c are open to interpretation since they do not require an explicit link to implantable devices to be specified, nor the extent to which it aids or continues to be critical to the implantable device.

This has resulted in items on the PL that arguably meet the criteria but that are potentially at odds with the purpose of the PL.

4.3.2.6 Apparent consequences of the listing process

Additionally, there is evidence that assessment against the criteria are not always effectively and consistently applied, leading to poor outcomes for the PL. The Department noted that the application assessment is often performed by individual clinicians with a focus on the absolute clinical benefits of the product with limited awareness of any cost implications of the decision – i.e. it is not a robust assessment of the extent to which the product meets the criteria and whether more appropriate funding mechanisms might exist from an efficiency perspective.

There was one example where rapid growth in usage of a product occurred in the months immediately after its introduction to the PL. A competitor successfully challenged the introduction on the basis that it did not meet the criteria, and the item was subsequently removed.

That the competitor undertook this challenge indicates that there is a commercial advantage for an item such as this to be funded through the PL compared to it being included within case based or bundled payments. As a consequence, the PL may not be the most clinically efficient means of funding low-cost high-usage items.

Parallels can be drawn between this incident and the recent introduction of topical skin adhesives, which was similarly followed by a large increase in total benefits paid in a short time.

Furthermore, there was evidence that large increases in the amount of benefits paid for certain products were driven by reclassifying existing products into higher benefit subgroups or suffix groupings, without any evident change to the product itself. Instances were seen where this has resulted in the minimum benefit amount per item increasing by up to 400%. It was suggested that this may be reflective of the process by which a single new product is listed at a new, more expensive suffix. This creates a comparator which other products previously listed at a lower amount can use to apply for a reclassification without necessarily having to justify the commensurate increase in cost that this represents. Examples of these are discussed further in Section 4.5.2.

Finding 4.3.2 (3)

For a number of general use items, it is commercially beneficial for the manufacturer if the item is funded through the PL. Evidence for this includes:

- high levels of usage – including increased usage since listing (discussed in Section 4.4);
- cases where benefit amounts have increased significantly with no reduction in usage (discussed in Section 4.5); and
- an example where a manufacturer sought the removal of a competitor's product from the PL as its listing was giving the competitor a commercial advantage.

That items have been listed on the PL but do not meet the criteria strongly suggests that there are issues with the listing process.

4.4 Usage

The general approach for this part of the analysis was to analyse the HCP1 data and to discuss with clinical subject matter resources for reasonable explanations behind usage and total benefit amount observations. The report highlights the situations where there may be a residual issue with the PL.

Fundamentally, the concern under investigation is that using PL as a funding mechanism may not send a direct price signal to hospitals, so:

- Usage of the item over and above the minimum level necessary to ensure patient outcomes is not disincentivised; and/or
- There may be higher than necessary usage of more expensive versions of equivalent products, including when they provide little/no clinical benefit over cheaper alternatives.

The approach was to:

- Identify high-volume items which have seen significant increase in usage since listing;
- Match the use of prostheses with associated Diagnosis-Related Group (DRG) code or Medicare Benefits Schedule (MBS) items to eliminate cases where the change in usage of the prosthetic item is in direct correlation to the change in broader clinical procedures, and to identify any low-risk procedures that are costing more than they might;
- Compare differences of usage between hospitals for similar procedures, which might imply drivers behind usage not concerning clinical need;
- Identify pairs or groups of items which seem to be of similar purpose and have had complementary movements in usage at similar times; and
- Discuss observations with clinical subject matter resources.

This component is intended to address the Terms of Reference item 2.

In this analysis, evidence was considered at a group, subgroup, suffix and billing code level. Both usage and benefits paid through time were compared at an absolute level and per separation. Areas were identified where the increase in usage exceeds that of similar products or that which might be expected given changes in the occurrence of the underlying procedures.

4.4.1 General trends in GM category

The GM category of the PL saw significant increases in utilisation and total benefits paid each year over the period from FY14 through to FY19. In this period, there was an 11% compound annual growth rate (CAGR) in the number of items used per year and a 9% CAGR in the total benefits paid. More recently, from FY18 to FY19 the growth in utilisation of items in the GM category was 15%, although the corresponding growth in total benefits paid was lower, at 3%, due to decreases in the average benefit amounts paid per item. The following figures show the total number of PL items used and total PL benefits paid for the GM category from FY14 to FY19, with

Table 7 and Table 8 showing the growth figures for the same period.

Figure 6 – GM – Total Prosthetic Items

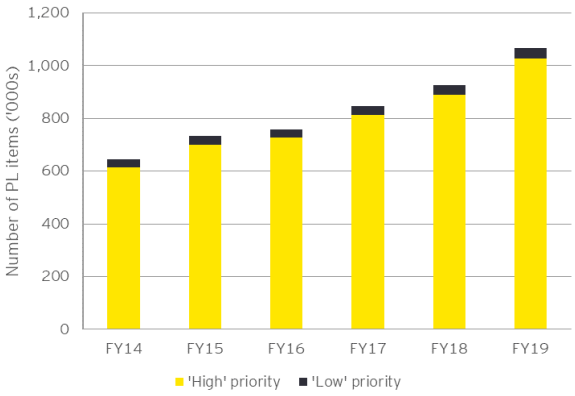


Figure 7 – GM – Total Prostheses Benefits

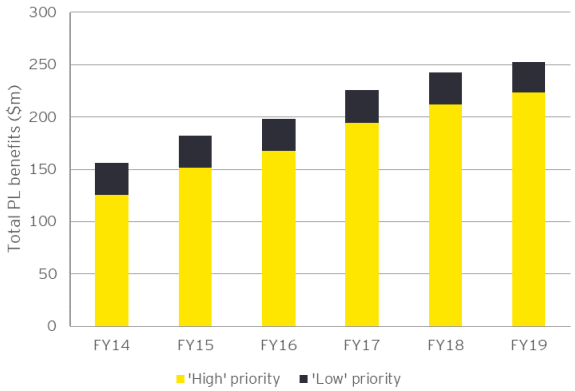


Table 7 – GM - growth in prosthetic items

Total Prosthetic Items	Annual growth rates (over previous year)					Compound Annual Growth Rate (CAGR)
Year	FY15	FY16	FY17	FY18	FY19	FY14 – FY19
GM	14%	4%	11%	10%	15%	11%
'High' priority	14%	4%	12%	10%	15%	11%
'Low' priority	5%	-3%	9%	8%	4%	5%

Table 8 – GM - growth in prostheses benefits

Total Prostheses Benefits	Annual growth rates (over previous year)					Compound Annual Growth Rate (CAGR)
Year	FY15	FY16	FY17	FY18	FY19	FY14 – FY19
GM	16%	9%	14%	7%	4%	10%
'High' priority	21%	11%	16%	9%	6%	12%
'Low' priority	-1%	-1%	3%	-2%	-6%	-1%

It is evident that the 'High' priority items made up the majority of all items and benefits paid for the GM category, comprising 96% and 89%, respectively. It is also noted that the 'Low' priority items experienced significantly lower growth in items each year than the 'High' priority group, with an overall decrease in benefits seen most years. This suggests there would be little additional benefit from a further review into the 'Low' priority GM items.

Within the 'High' priority GM items there are 19 product groups, 4 of which (Staples & Tackers, Internal Adhesives, Matrix and Ligating Devices, highlighted in red below) made up 88% of all benefits paid in FY19 in respect of the 'High' priority GM items and 93% of the growth in benefits from FY14 through FY19. The fourth largest group, '03.08.03 – Ligating Devices', contributed more total benefits than the remaining 15 groups combined in FY19. Total benefits by product group for the 'High' priority GM grouping is summarised in Table 9 below, including the CAGR observed over the FY14 – FY19 period.

Table 9 below shows the compound annual growth rates for each of these product groups over the period from the end of FY14 through to the end of FY19, summarising the rate at which benefits increased each year on average above and beyond the previous year. An adjusted version of this rate is also shown, accounting for the simultaneous growth in the underlying number of separations over the same time period. This adjusted rate therefore reflects the rate of growth in the amount of benefits per separation over time. This shows the extent to which the amount of benefits was growing faster than the number of separations.

Table 9 – 'High' priority GM – Total PL benefits in FY19 by product group

Product Group	Total PL benefits FY19 ($m)	Proportion of total 'High' priority FY19	CAGR FY14 – FY19	CAGR (adjusted)^ FY14 – FY19
03.02.01 - Infusion Ports	0.27	0.1%	13%	10%
03.02.02 - Infusion Pumps, Balloon Based	5.80	2.6%	12%	9%
03.02.03 - Infusion Pumps, Battery Powered	4.39	2.0%	26%	23%
03.02.04 - Infusion Pumps, Spring Powered	0.75	0.3%	-23%	-25%
03.02.05 - Infusion Pump Accessories	0.96	0.4%	8%	5%

Product Group	Total PL benefits FY19 ($m)	Proportion of total 'High' priority FY19	CAGR FY14 – FY19	CAGR (adjusted)^ FY14 – FY19
03.02.06 - Pharmaceutical Beads	0.11	<0.1%	-15%	-17%
03.05.01 - Occluder Pin	<0.01	<0.1%	-22%	-24%
03.05.02 – Powder	0.72	0.3%	40%	36%
03.05.03 - Sponges	0.62	0.3%	0%	-2%
03.05.04 - Pliable Patches	3.01	1.3%	4%	1%
03.05.05 – Matrix	30.31	13.6%	15%	12%
03.05.06 – Foam	2.12	1.0%	N/A –no usage in FY14	
03.08.01 - Adhesion Barriers	4.58	2.0%	3%	0%
03.08.02 - Internal Adhesives	42.98	19.2%	28%	24%
03.08.03 - Ligating Devices	27.31	12.2%	5%	2%
03.08.04 - Staples & Tackers	95.92	42.9%	11%	8%
03.08.05 - Polypropylene/Polyester Mesh	3.65	1.6%	-3%	-6%
03.08.10 - Anastomosis Clip	0.03	<0.1%	-12%	-14%
03.08.11 - Dynamic Wound Closure Devices	<0.01	<0.1%	-1%	-4%
Total 'High' priority	**224.00**	**100%**	**12%**	**9%**

^Adjusted for growth in the number of separations

A disproportionate amount of the growth in total benefits paid for this 'High' priority GM category was due to a small number of individual billing codes. As at February 2020, there were 529 individual billing codes in the 'High' priority GM category. Out of these 529, just 10 items accounted for 70% of the dollar growth in total benefits over the five years from FY14 to FY19, despite only accounting for 27% of total benefits in FY14 (now up to 46% in FY19). This is summarised in Table 10 below.

Table 10 – 'High' priority GM – Summary of growth for top 10 items

Group	Proportion of total PL benefits FY14	Proportion of total PL benefits FY19	Total growth in PL benefits FY14 – FY19 ($m)	Proportion growth in PL benefits FY14 – FY19 ($m)	CAGR FY14 – FY19
Top 10 growth	27%	46%	68.5	70%	25%
All other items	73%	54%	29.5	30%	6%
Total 'High' priority	**100%**	**100%**	**98.0**	**100%**	**12%**

Finding 4.4.1

The 'High' priority 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.

In the remainder of this review the items primarily responsible for driving this high growth were analysed. That items contributing to increased benefit payments were selected is therefore not biased in the sense that the effect of these items was far outweighing any items with an offsetting impact.

4.4.2 Sudden growth since listing

Sudden growth in usage within a group following the inclusion of a new product on the PL may indicate that the growth is driven by its availability on the PL and not due to changes in clinical needs. It may alternatively be indicative of continued usage of an item that had previously been funded differently, or a transfer of usage from an alternative product on the PL.

Such transfers may not represent cause for concern where they are associated with improvements in clinical procedures and/or patient outcomes relative to any increase in cost. It is noted that differentiating between these causes is difficult without data on usage levels (funded through alternative arrangements) prior to an item's introduction to the PL as a baseline. It is also noted that growth driven by availability of an item on the PL is not necessarily problematic where the clinical need may not have previously been well-met by the prior funding arrangements and the resultant clinical benefit from increased usage is commensurate with its cost.

There have been several instances evident in the 'High' priority GM category where levels of usage increased rapidly following an item's introduction to the PL. These examples are discussed here to highlight incidences with a significant potential for driving inappropriately high benefit payments.

4.4.2.1 Internal Adhesives – Topical skin adhesives

Significant growth in usage and benefits for the GM category of the PL was driven by the introduction of topical skin adhesive products to the '03.08.02 – Internal Adhesives' group since February 2017. Following the introduction of these products, total benefits paid each year for the '03.08.02.01 - Adhesive ≤2ml' subgroup to which they belong grew by $15.6m, a 527% increase. Analysis of specific products within this subgroup indicates that this was almost entirely due to these topical skin adhesive products alone. For further information refer to the case study in Section 5.2.1.

From consultation submissions and clinical subject matter resources, it is apparent that these products represent alternatives to other skin closure techniques such as skin sutures, which are covered under general hospital payment methods and have existed and been in wide use for many years prior to their introduction to the PL. The review does not have access to usage data for these items prior to their inclusion on the PL, however, the substantial increase in a short period of time suggests that total benefits are now higher than might be possible (for equivalent clinical outcomes) through alternative funding mechanisms or with increased usage alternative products.

4.4.2.2 Foam

'Foam' haemostatic devices were first introduced to the PL in February 2013. As shown in Figure 8, minimal usage was seen for the group until FY17 following the introduction of new products on the PL. By the end of FY19, usage increased significantly to almost 15,000 items per year, up from under 100 items per year in FY16. This corresponded to an increase in benefits from under $10,000 per year to over $2.1m per year, of which 98% was attributable to one product. Foam products were available for use in surgery prior to inclusion on the PL but were funded as part of case based or bundled payments.

In this instance, the listing of new products resulted in significant additional usage being created on the PL for a group that previously only had very limited usage. Consequently, this group made material contributions to the total annual benefits for the GM category in FY19. Clinical subject matter resources suggested that due to its listing, there is a reasonable possibility that this increase in usage is beyond reasonable clinical benefit.

It was also suggested in stakeholder consultation that some of these items are available internationally at significantly lower prices than the PL benefit amount of $142 per unit.

As such, ’03.05.06 – Foam’ represents a group of high volume and potentially over-priced, consumables which may be susceptible to usage inflation of use beyond clinical requirements.

Figure 8 – Foam – Total PL item usage

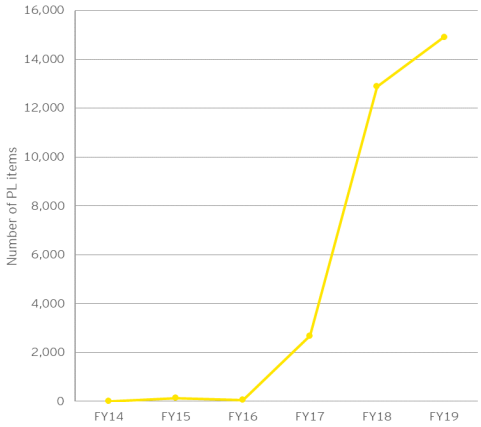
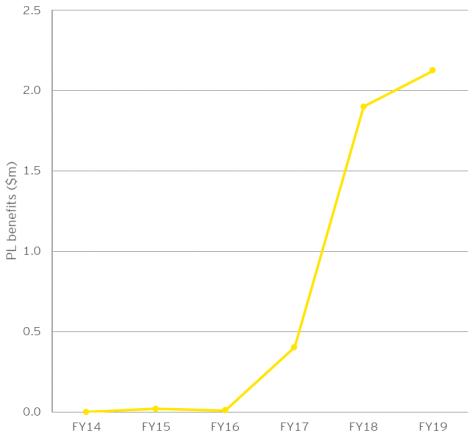


Figure 9 – Foam – Total PL benefits



4.4.2.3 Staples, Reinforcer

Further significant growth in usage and benefits for the GM category of the PL was also seen following the addition of a single new product to the ‘03.08.04.03 – Staples, Reinforcer’ subgroup of the ’03.08.04 – Staples & Tackers’ group, part of the ’03.08 – Closure Devices’ subcategory. One item contributed almost $6.7m in benefits within 11 months of its introduction to the list. Again, this item was available for use in surgery prior to its inclusion on the PL but was funded as part of case based or bundled payments.

In this case, the listing of new products resulted in both an increase in usage and an increase in average benefit per item. This may be reflective of improvements in the technology and so may not be problematic if these improvements led to improved clinical outcomes.

4.4.2.4 Staples, Non-bone with Disposable Applier

The introduction of a single product resulted in a very significant and rapid increase in usage for the ’03.08.04.04 – Staples, Non-bone with Disposable Applier’ subgroup, a group which experienced decreases in usage and benefits paid previously.

Finding 4.4.2

There have been a number of items which experienced significant and sustained growth in their usage since being listed.

It seems likely that the growth in usage since their listing was driven by the availability of the product on the PL rather than by changes in clinical needs and it is evident that their listing significantly contributed to the overall growth in the GM category of the PL, with two products accounting for 18% of the growth in the ‘High’ priority GM benefits between FY14 and FY19.

4.4.3 Differential usage of complementary items

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.

It is noted that there may be a number of reasons for an apparent preference for larger volume/size versions of some of these products, despite the accompanying increased cost. One potential factor that could drive this behaviour is the increased convenience afforded by use of a larger size than is strictly needed, particularly in cases where the actual required size/volume needed is not known at the outset. It is also acknowledged that this added convenience might be considered as driving other secondary clinical and cost saving benefits such as through reductions in operating times. However, such secondary benefits are hard to quantify and verify without detailed and targeted analysis.

4.4.3.1 Matrix

Within the '03.05.05 – Matrix' group of GM products there were clear, large differentials in the relative levels of usage between the different size subgroups. This appears to have driven higher benefits than might otherwise be necessary. This was seen in particular for the liquid subgroups of matrix products, which comprised the largest drivers of benefits for the group. In this case, there were significant trends towards greater relative usage of the larger volume, more expensive items over the period from FY14 through FY19.

This apparent strong and increasing preference for the larger, more expensive varieties does not appear to be adequately explained by pure clinical need. As a result, it may be indicative of the impact of a lack of disincentives against usage of larger volumes when not necessarily required, leading to wastage and contributing to higher benefits being paid. This is discussed in greater detail in the case study 'Matrix' in Section 5.4.

4.4.3.2 Pliable Patches

A similar situation can be seen for the '03.05.04 – Pliable Patches' group. Within this group, there are three subgroups differentiated according to the size of the patches, namely '03.05.04.01 – Absorbable $\leq$50cm^2', '03.05.04.02 – Absorbable 51cm^2 – 75cm^2' and '03.05.04.03 – Absorbable >75cm^2', with average benefits ranging from \$30 to \$74 between these subgroups (discussed further in Section 4.5.3). Figure 10 shows 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.

When looking at usage of the various sizes of pliable patches by hospital owners, it is noted that there was a significant difference in the relative usage of the larger and smaller patches between two large hospital groups. Specifically, the largest size patches made up 59% of the total usage for one hospital group in FY19, whereas they made up 72% for the other in the same year. Conversely, the smallest size patches made up 32% for one hospital group and only 18% for the other. 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.

Figure 10 – Pliable patches – Total PL items per 1,000 separations

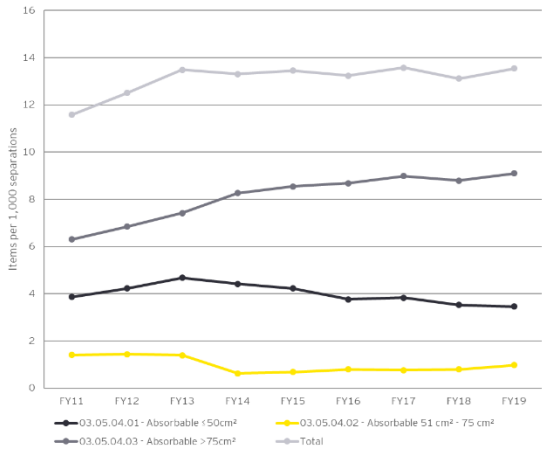
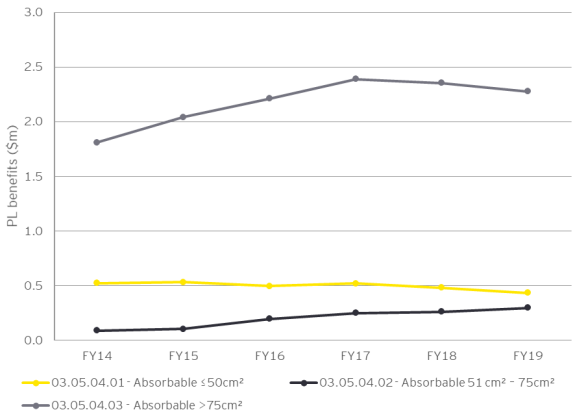


Figure 11 – Pliable patches – Total PL benefits by subgroup



Within the '03.05.04 – Pliable Patches' group, there are multiple suffixes, all with different associated minimum benefit amounts. Since FY16, the 'Antimicrobial, Low Antigenicity, Micro-fibrous' (henceforth, Micro-fibrous) suffix was the largest contributor to total PL benefits paid for this subgroup, ahead of the 'Antimicrobial, Low Antigenicity' (henceforth, Standard) suffix. The Micro-fibrous version has a minimum benefit amount around three times higher than the Standard version ($98 and $33-$34 respectively). Additionally, growth in the usage of the Micro-fibrous version was consistently higher than the growth in the Standard version.

When looking at which MBS item codes are associated with usage of the Micro-fibrous and Standard versions of the patches in a separation, there was a significant overlap in the top 5 MBS item codes as shown in Table 11, suggesting that the Micro-fibrous and Standard versions could potentially be items that are used in the same situations for the same purpose. Clinical subject matter resources suggested that the Micro-fibrous version is probably more effective for significant bleeding, but it is also noted that their usage is likely above and beyond only procedures with significant bleeding that require the Micro-fibrous version.

Table 11 – Pliable Patches – Micro-fibrous vs Standard – Total FY19 PL benefits by item

Micro-fibrous			*Standard*		
MBS item code	**Abridged Description***	**Total PL benefits (FY19)**	**MBS item code**	**Abridged Description***	**Total PL benefits (FY19)**
37210	Prostatectomy	$125,043	51011	Spinal decompression or exposure	$36,679
41671	Nasal septum, septoplasty, submucous resection	$65,713	39709	Craniotomy	$29,298
37211	Prostatectomy	$52,223	16522	Management of labour and birth	$24,446
16520	Caesarean section and post-operative care	$46,384	16520	Caesarean section and post-operative care	$23,459
16522	Management of labour and birth	$45,955	37210	Prostatectomy	$22,596

4.4.3.3 Internal Adhesives

Significant growth in usage and benefits for the internal adhesive group of products was driven by a single product, which represents one of the top 10 items contributing the most growth across all of the 'High' priority GM products, associated with a $6.4m increase in annual benefits from FY14 to FY19. In particular, it is noted that there was an apparent strong preference for the larger, more expensive size version of this product (which contrasts to similar competitor products), which may be suggestive of the PL leading to adverse benefit amount outcomes. The observed trends may be suggestive of the lack of disincentives against potentially unnecessary usage of these products brought about by their availability on the PL and their simultaneous broader applicability contributing to expanding usage.

Finding 4.4.3 (1)

There are numerous groups in which similar items differing by a characteristic (such as size) have different minimum benefit amounts. In some cases, the usage of these items differed significantly, with some skewed towards usage of the more expensive items, such as the larger versions of matrices, pliable patches, and internal adhesives. Additionally, within the larger pliable patches, PL benefits paid for the more expensive micro-fibrous version are higher than benefits paid for the cheaper Standard version.

It is likely that in many cases usage of the more expensive option is more than sufficient to meet clinical needs and is therefore not the most efficient option from an overall healthcare costs perspective.

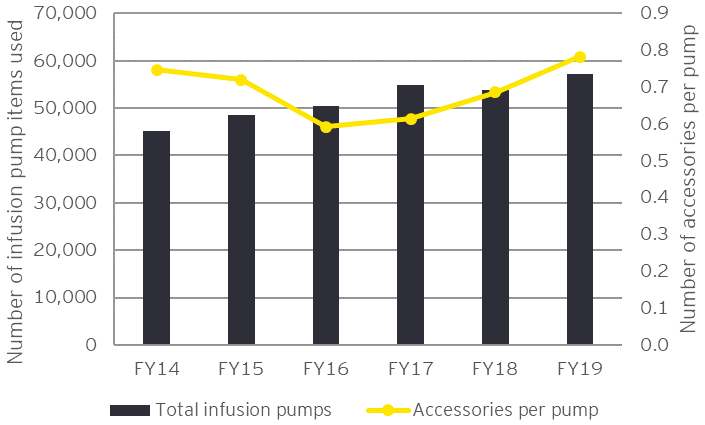
4.4.3.4 Infusion Pump Accessories

This product group encompasses kits, administration cassettes, reservoirs, sets and other accessories for infusion pumps. Many of these accessories are intended for use with battery powered infusion pumps. Infusion Pump Accessories included in the GM category of the list are typically single-use, low benefit amount per item products. Usage of infusion pump accessories was primarily from within the '03.02.05.02 – Administration Cassette' and '03.02.05.04 – Administration Set' subgroups, which together represented 91% of all item usage for the group.

The minimum benefit amount payable per item is significantly higher for administration cassettes than administration sets. This resulted in usage of administration cassettes accounting for 60% of total benefits paid for all infusion pump accessories in FY19 compared to only 14% for administration sets, despite otherwise comparable levels of usage.

Figure 12 shows the level of usage of infusion pump accessories relative to the level of usage of the infusion pumps themselves. The total number of pumps includes usage across all three infusion pump groups – balloon-based, battery-powered and spring-powered – and is not limited to just those pumps for which related accessories are included separately on the PL. This shows that, following a dip in usage in FY15 and FY16, the accessory usage grew faster than the underlying level of growth in the infusion pumps themselves.

Figure 12 – Infusion pump accessories – Number of accessories used per infusion pump, overall



Stakeholders raised concerns that infusion pumps are being purchased through the PL and being returned to the hospital's capital equipment stock. In this case, the difference in infusion pump usage and infusion pump accessory usage could be due to infusion pumps being reused after their purchase from the PL, contrary to the listing criteria.

There are cases where an infusion pump and its associated accessories showed different usage patterns. In these cases, while the usage of the pumps was relatively stable since FY14, the number of accessories used per pump increased significantly over the same period. In some cases, many hundreds or even thousands of infusion pump accessories were used for each equivalent infusion pump.

Finding 4.4.3 (2)

There have been a number of examples where the use of an infusion pump accessory did not align with the use of the pump itself. This may be indicative of:

- more accessories being used than is clinically sufficient;
- accessories being used for purposes not specified by their listing; or
- the pump being reused after their initial purchase from the PL.

4.4.4 Usage per separation and type of procedure

Instances were observed where the number of items used per separation increased over time. Increases in the number of items used per separation indicates growth in usage outstripped growth in the underlying number of separations for private patients in Australia.

In these instances, it is unclear whether the usage of more items resulted in better clinical outcomes, such as due to advancements in surgical techniques or clinical practice, or whether it was a consequence of a lack of disincentives against use of items above clinical needs potentially due to the nature of the PL. Increases may also partially reflect changes to the underlying case mix of the separations. However, it is noted that this alone is unlikely to adequately explain the extent of growth seen in some products. These examples are summarised below.

4.4.4.1 Staples & Tackers

The usage per separation for the staples and tackers group increased steadily since FY11, as indicated in Figure 13, at a CAGR of 12%. Based on initial consultation submissions and discussion with clinical subject matter resources, recent shifts and advancements in clinical practice towards keyhole surgery over open surgery were flagged as a key contributor to growth in the use of these items. This is supported by the fact that bariatric surgery drove 69% of all growth in usage since FY11. However, the level of growth seen for usage of staples and tackers in bariatric surgery was substantial even after adjusting for growth in the number of procedures, with usage per separation growing at a rate of 8% p.a. (CAGR) since FY14 (when bariatric surgery was first introduced to the MBS as a specific grouping). Furthermore, significant growth was also seen outside of bariatric surgery, meaning this alone does not explain the entire extent of growth. This is discussed further in the case study 'Staples and Tackers' in Section 5.3.

Figure 13 – Staples & Tackers – Items per 1,000 separations

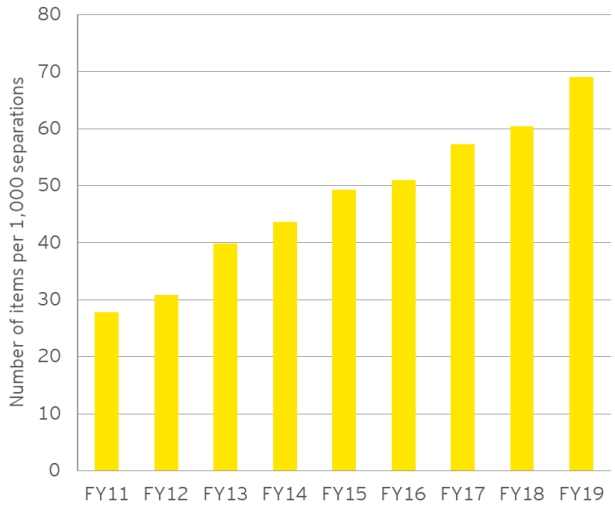
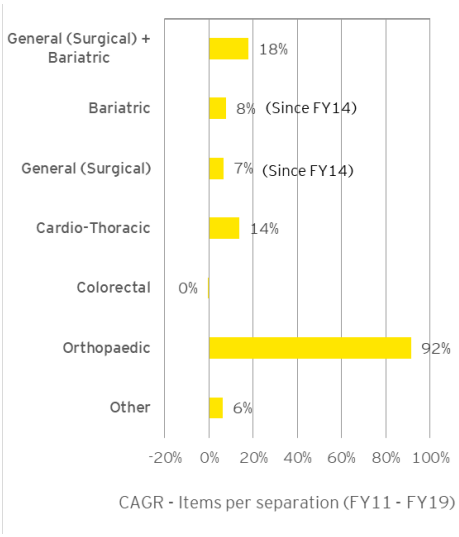


Figure 14 – Staples & Tackers – CAGR, items per separation (FY11 – FY19), by grouping of primary MBS code (in order of total items used)



4.4.4.2 Internal Adhesives (excluding topical skin adhesives)

Recent high growth in usage per separation for internal adhesives was largely driven by the introduction of topical skin adhesive products to the group, as discussed in Section 4.4.2. Usage per separation was also growing at a significant rate in the '03.08.02 – Internal Adhesives' group more generally outside of these topical skin adhesives with an overall CAGR of 18%. The largest types of procedures driving this growth were general surgical and bariatric surgery procedures, which combined accounted for 51% of the growth in usage since FY11. High annual growth rates were generally observed across a range of procedures. The high level of growth that was seen across a wide variety of types of procedures shows that the rate of usage of internal adhesive products grew significantly faster than general levels of growth in surgical procedures. This may be suggestive that the availability of these products on the PL was driving levels of usage beyond clinical needs. Further discussion of these products is provided in the case study in Section 5.2.2.

Figure 15 – Internal Adhesives (excl. topical skin adhesives) – Items per 1,000 separations

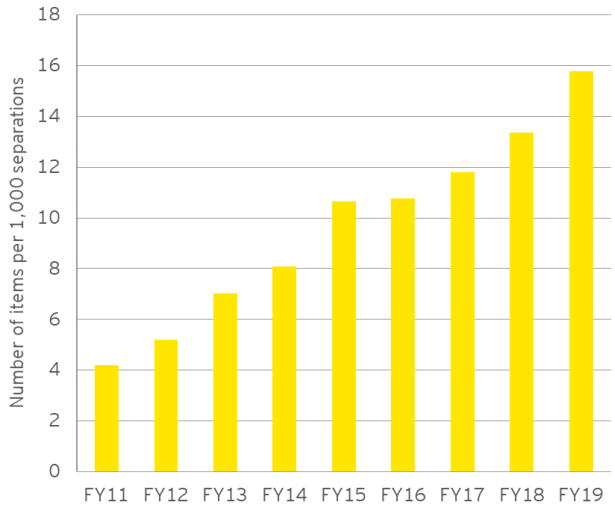
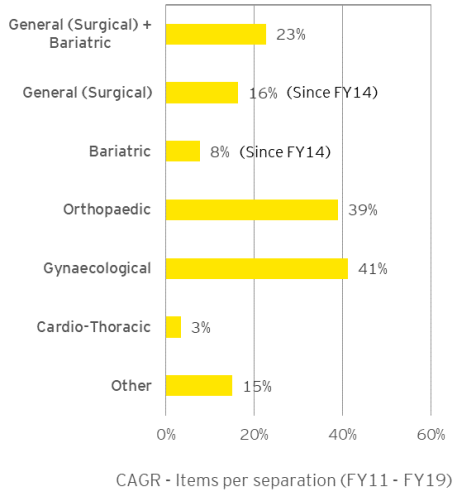


Figure 16 – Internal Adhesives (excl. TSA) – CAGR, items per separation (FY11 – FY19), by grouping of primary MBS code (in order of total items used)



4.4.4.3 Infusion Pumps, Battery Powered

There was significant recent growth in usage per separation for battery-powered infusion pumps, with relatively low usage over from FY11 to FY15. Overall, usage per separation for these infusion pumps grew at a 36% CAGR from FY11 to FY19.

The majority of usage for these products related to orthopaedic procedures, based on an analysis of MBS item codes associated with usage of battery-powered infusion pumps. In FY19, 80% of all usage related to orthopaedic procedures, up from 41% in FY11. Orthopaedic procedures accounted for 83% of all growth in usage over the same time period, with usage per separation growing at a 49% CAGR since FY11.

Similar to the other examples mentioned previously, this high level of growth across a variety of procedures may be suggestive of increased usage being driven by availability of these products on the PL rather than purely by clinical need.

Figure 17 – Infusion Pumps, Battery Powered - Items per 1,000 separations

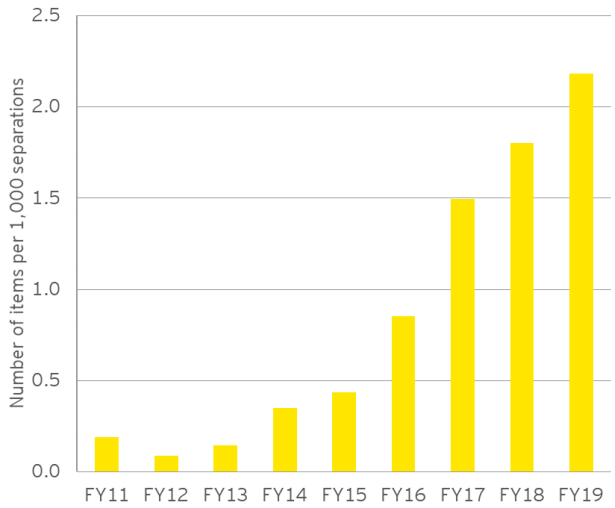
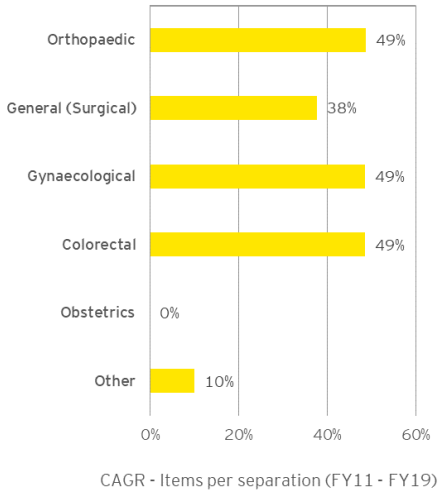


Figure 18 – Infusion Pumps, Battery Powered – CAGR, items per separation (FY11 – FY19), by grouping of primary MBS code (in order of total items used)



4.4.4.4 Powder

Usage per separation grew at a significant rate for 'Powder' haemostatic devices since FY11, increasing by 315% up to FY19, equivalent to a 19% CAGR, as shown in Figure 19.

These powder haemostatic devices were primarily used in cardio-thoracic and neurosurgical/spinal surgery[8] procedures, representing 31% and 33% of total usage in FY19, respectively. As indicated in Figure 20, high rates of growth in usage per separation were experienced across a variety of types of procedures. Particularly high levels of growth were also seen for general surgical procedures and orthopaedic procedures, collectively accounting for 12% of total usage in FY19, up from 2% in FY11.

Similar to the other examples mentioned previously, this high level of growth across a variety of procedures may be suggestive of increased usage being driven by availability of these products on the PL rather than purely by clinical need.

[8] Spinal surgery was split out from neurosurgery on the MBS in 2018. They have been combined together in this analysis due to spinal surgery only having a single financial year of data available.

Figure 19 – Powder - Items per 1,000 separations

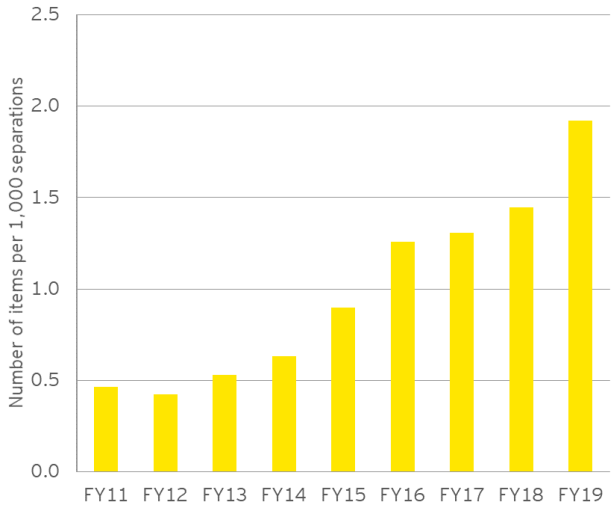
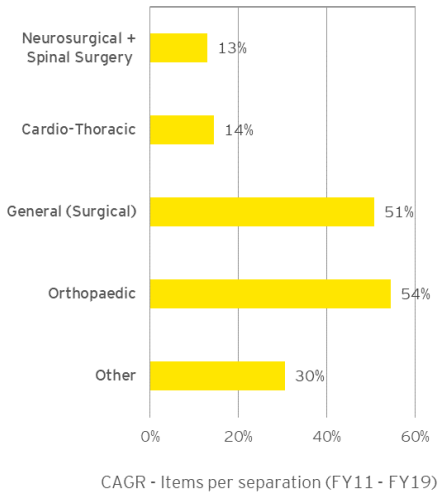


Figure 20 – Powder - CAGR, items per separation (FY11 – FY19), by grouping of primary MBS code (in order of total items used)



4.4.4.5 Matrix

Usage per separation also grew at a significant rate for 'Matrix' haemostatic devices since FY11, shown in Figure 21 below. As discussed in the 'Matrix' case study in Section 5.4, this was primarily due to increased usage of the larger volumes of liquid matrix products. Overall, usage per separation for these matrix haemostatic devices grew at a 14% CAGR from FY11 to FY19.

High rates of growth in usage per separation was seen across a variety of types of procedures for these matrix products, as indicated in Figure 22. Notably, neurosurgical/spinal surgery procedures represented the single largest category of usage, constituting 34% of total usage in FY19 and 34% of total growth in usage from FY11 to FY19.

Similar to the other examples mentioned previously, this high level of growth across a variety of procedures may be suggestive of increased usage being driven by availability of these products on the PL rather than purely by clinical need.

Figure 21 – Matrix - Items per 1,000 separations

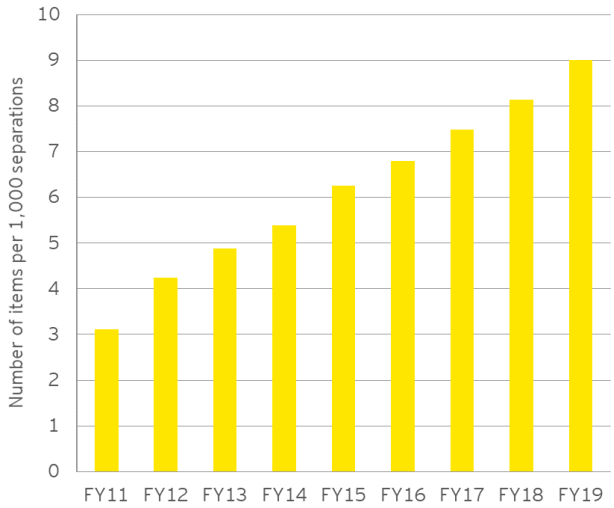
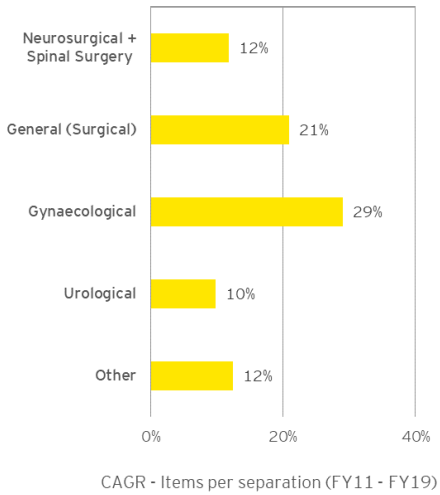


Figure 22 – Matrix - CAGR, items per separation (FY11 – FY19), by grouping of primary MBS code (in order of total items used)



Finding 4.4.4

There have been a number of examples of above-trend usage growth that isn't prima facie explained by increases in the number of procedures. In all cases, the level of growth was such that it seems unlikely that changes in the nature of procedures or in the case mix are sufficient to explain all of the growth. This suggests that at least some of the growth must have been due to an increase in the number of items per separation within the same procedures.

This suggests that there was some element of over-use occurring in these groups.

4.4.5 Differential usage by hospital groups

Differential usage across hospital groups may be reflective of the mix of procedures undertaken and the preferences of the physicians practicing within the group. However, it may also be indicative that the PL does not disincentivise the use of items more than clinical needs, or that manufacturers are interacting differently with different hospitals and clinicians.

In this analysis, focus was placed on looking at hospital groups rather than individual hospitals themselves. Ideally, analysis of individual hospitals would be helpful to investigate how contracting differences and clinical preferences may have been influencing usage of these GM items. Due to the large number of items and hospitals, this would have been a significantly large analysis and not feasible given the constraints of this review. Looking at a hospital group level, it does appear evident that there were differences between some of these hospital groups that may not immediately be explainable by differences such as case mix and may be indicative of variation between clinical choices or preferences.

A number of instances were identified where there were apparent differences between hospital groups in the usage profile and growth trends of products from the 'High' priority GM category. These examples may be at least partially explainable by differences between hospital owners in factors such as case mix and type of facility, but may also represent instances where usage was influenced by other factors, including possible adverse incentives or a lack of disincentives, leading to higher benefits being paid.

Analysis of PL usage and benefits for the 'High' priority GM category items was conducted across the top 8 private hospital groups, all other private hospital owners combined and private treatment in public hospitals.

4.4.5.1 Overall – 'High' priority GM

Three large hospital groups together accounted for 58% of the total benefits paid for 'High' priority GM items in FY19. Importantly, these three hospital groups experienced the three highest rates of growth in the number of items used per separation over the period from FY11 through FY19, at around 8% to 10% each. These were over double the growth rate seen for all other hospitals in aggregate. Together, these hospital groups were the largest contributors to growth in PL benefits for these items both in dollar value and percentage growth terms and accounted for 62% of the total growth in benefits over the period while accounting for only 36% of the total growth in number of separations.

Furthermore, there were significant variations in the rate of PL item usage for these 'High' priority GM items between the various hospital groups. Some hospital groups showed comparatively greater overall usage per separation, whilst others showed a lower overall usage per separation. It is also evident that the top 8 hospital groups showed substantially higher usage per separation than was seen on average for all other smaller private hospital groups.

It is noted that there could have been a number of factors influencing the disparity in growth rates and level of usage per separation between each of these hospital groups, and it is not possible to distinguish these factors in this analysis. This includes differences in procedures undertaken and case mix between hospital groups. It also highlights that the rate of PL item usage per separation for the 'other private hospitals' group may have been lower because of the inclusion of smaller or more specialised facilities that do not provide prosthetic treatments. Additionally, the 'public hospitals' group may have understated benefit and item usage levels due to lower levels of 'completeness' in the reported HCP1 data, as discussed in Section 3.2.2.1, to the extent that the number of separations were themselves similarly 'incomplete' (this has not been assessed).

There was a range of average benefit amounts evident between the various hospital groups, reflecting differences in the mix of prosthetic items being used by each hospital group. This may have been due to differences in case mix between hospitals (and hospital groups) and potential differences in preference for certain items or types of treatment. Two hospital groups represented the highest average benefit amounts, with all private hospital groups showing a higher average benefit per item than seen for private treatment in public hospitals.

4.4.5.2 Matrix

Within the '03.05.05 – Matrix' group, there were clear differences between some hospital groups in the extent of apparent preference for larger, more expensive versions of products on the PL. For the liquid matrix subgroups of these matrix products, a preference for larger volumes was seen generally across the board for private hospital groups that was not fully replicated across instances of private treatment within public hospitals. Clinical subject matter resources suggested there is no obvious reason why private treatments in public hospitals would clinically require smaller sizes, suggesting that the increased preference for larger volumes may not have been strictly driven by clinical needs alone. A preference for larger, more expensive versions was also particularly evident for non-liquid matrix products, with the exception of one hospital group.These examples are discussed in greater detail in the case study 'Matrix' in Section 5.4.

4.4.5.3 Internal Adhesives - Liquid

Significant differences in the rate of item usage per separation were evident between some of the hospital groups in relation to products from the '03.08.02 – Internal Adhesives' group. These items were used at a significantly higher rate within the larger hospital groups than across the smaller hospital groups. Additionally, usage of topical skin adhesive products in two hospital groups was particularly high compared to other hospitals. One hospital group showed a usage per separation rate for these items over 50% more than that for the hospital with the next highest usage per separation rate, and over 330% more than the 'other private hospitals' group, which includes the smaller hospital owners.

Consultation submissions raised concerns about internal adhesive products, particularly around the topical skin adhesives, due to their temporary and general use nature and that their availability on the PL might be driving greater usage of these products over cheaper alternatives. A greater preference in some of these hospital groups for usage of internal adhesives on the PL over alternative products, or for usage of internal adhesives in greater volumes, may be indicated by the differences seen in usage rates. It may also be explainable (at least partially) by differences in case mix or other clinical factors between facilities themselves. Further discussion of these products is provided in the case study in Section 5.2.

4.4.5.4 Staples & Tackers

The high levels of growth seen across the '03.08.04 – Staples & Tackers' group (an increase in annual benefits of over $39m in the period from FY14 to FY19) was not uniformly experienced across the

various hospital groups analysed. Notably, two large hospital groups have experienced the largest rates of growth out of all the groups examined, at rates significantly in excess of the smaller hospital groups. This large difference may be suggestive of other factors that influenced the increased usage of these products, such as increased usage of these PL-funded items in preference to other, potentially cheaper alternatives and not necessarily in line with specific clinical need. This is discussed in the context of the general usage trends in the '03.08.04 – Staples & Tackers' group as part of the case study 'Staples and Tackers' in Section 5.3.

4.4.5.5 Infusion Pumps

Given the issues regarding infusion pumps and the listing criteria (Section 4.3.2.2) and the anomalies observed around the consistency of usage with infusion pump accessories (Section 4.4.3.4), there is additional analysis of the usage of infusion pumps by hospital group within the case study in Section 5.5.1.

There is variation between hospital groups in the number of infusion pumps used per separation. In addition, the choice of the types of infusion pumps used varies significantly between hospital groups.

Finding 4.4.5

The examples discussed above, at the overall 'High' priority GM level, and for matrices, internal adhesives, staples and tackers and infusion pumps, illustrate significant difference in growth and usage of these items between hospital groups. Whilst some of this was undoubtedly driven by differences in procedures and case mix between hospitals, it also suggests that hospital contracting arrangements and hospital and clinician preferences may have been having an impact on usage of these items.

This suggests that, in these situations, the PL may not be the most efficient funding mechanism for ensuring the most competitively priced items that achieve the required patient outcomes are being selected.

4.5 Benefit amounts

The general approach for this portion of the analysis was to:

- analyse the history of benefit amounts for items on the PL, including when these have resulted from a change in categorisation;
- compare benefit amounts for items within groups/subgroups/suffixes;
- compare benefit amounts on the PL with equivalent prices in the public health system; and
- conduct stakeholder consultation and seek input from clinical subject matter resources;

and then to overlay this analysis of benefit amounts with the relative usage levels of the items.

If there were any benefit amount anomalies, or usage patterns that did not respond as expected to differences in benefit amounts, then this could have been indicative that:

- Benefit levels did not directly relate to costs in the supply chain, and manufacturers were able to increase benefits because it would have been unlikely to result in reduced usage;

- The PL was reducing the level of competition between medical device manufacturers meaning that prices were higher than they would have been otherwise; or
- The structure of the list and the process for listing can be used as a way to increase benefit amounts.

Opportunities for improvement related to this component, as described in Section 6.2.1, are intended to address the Terms of Reference item 6.

4.5.1 Relationship between benefit amount and usage

In a competitive environment it is expected that an increase in benefit amount would result in decreased usage. If this relationship does not hold then manufacturers are not incentivised to apply for a reduction in benefits (or, alternatively, are incentivised to seek increases in benefits), meaning that benefit amounts may be higher than they would be otherwise.

A number of examples were found where the expected relationship between benefit amount and usage did not hold, i.e. that a significant increase in benefit amount was not accompanied by a decrease in usage. In most of these situations, increases in the minimum benefit amount were brought about as a consequence of reclassification of items on the PL, as opposed to a direct benefit amount increase to a given product subgroup or suffix. Examples of these are discussed further in Section 4.5.2.

4.5.2 Impact of listing process and categorisation

The process for listing and categorisation on the PL could be driving higher benefit amounts for items than would otherwise be expected. This can arise when items are relisted or moved to other parts of the list to achieve increased minimum benefit amounts, or by bundling products or replacing cheaper items with more expensive items, without necessarily offering any improvements in clinical outcomes.

There have been a number of examples of GM items that were reclassified into other subgroups or suffixes within the same subgroup leading to large immediate increases in the minimum benefit amount payable for these items. In many of these cases, it is not apparent whether there was any change to the underlying product which might justify the effective benefit amount increase.

4.5.2.1 Internal Adhesives – 'Rigid Delivery System' adhesive accessories

One key example with large impacts on total benefit payments was seen in the case of adhesive accessory products in the '03.08.02 – Internal Adhesives' product group. In February 2016, the minimum benefit amount per item for three of these adhesive accessory products increased by 416% from $31 to $160 following a reclassification of a number of products that had previously been listed under the 'Extender' suffix to the 'Rigid Delivery System' suffix. No other changes to the details of the product listings were made that would suggest that the product itself had changed. In February 2017 two further products were also reclassified as 'Rigid Delivery Systems', having previously been listed in the '03.05.05.05 – Accessory Extender' subgroup of '03.05.05 – Matrix'. This was accompanied by the same 416% increase in the minimum benefit amount per item.

Four out of these five products reclassified as 'Rigid Delivery Systems' saw continued large growth in utilisation in FY16 and FY17 despite the large increase in benefit amount. These five products collectively accounted for an increase in annual total benefits of over $2.2m over the period from FY14 to FY19, representing 86% of the $2.6m increase in annual total benefits for the whole '03.08.02.04 – Adhesive Accessory' subgroup over the same period.

4.5.2.2 Adhesion Barriers – 'Complex' gels/liquids

Growth in benefits was driven by the reclassification of one product to the 'Complex' suffix (previously having had no suffix) in the '03.08.01.04 – Gel/Liquid' subgroup of '03.08.01 – Adhesion Barriers'. This reclassification led to a 157% increase in the minimum benefit amount for the product. At the same time, a duplicate product was added to the list but for a different sponsor. When considering both of these products together, total usage continued to grow by 25% in the year.

4.5.2.3 Infusion Pumps, Balloon Based – Fixed flow rate

Five fixed flow rate balloon-based infusion pump products in the '03.02.02.01 – Fixed Flow Rate' subgroup were reclassified into the "Set" suffix (previously not listed with a suffix) in November 2019. This led to a 205% increase in the minimum benefit amount per item, increasing from $79 per item to $241 per item. Due to the recent nature of this change, data is not available on any potential impacts on usage for these items. These are discussed in greater detail as part of the case study in Section 5.5.

4.5.2.4 Infusion Pump Accessories - Kits

In February 2018, one product changed name and was reclassified from the '03.02.05.05 – Other' subgroup of '03.02.05 – Infusion Pump Accessories' to the '03.02.05.01 – Kit' subgroup. Due to this reclassification, the minimum benefit amount for the item increased by 54%, from $50 per item to $77. In the financial year following this benefit increase (FY19), total usage for this product increased.

4.5.2.5 Pliable Patches

In August 2015, the '03.05.04.01 – Absorbable $\leq$50cm^2' subgroup of '03.05.04 – Pliable Patches' was divided with the introduction of the '03.05.04.02 – Absorbable 51cm^2 – 75cm^2' subgroup. As a consequence, the minimum benefit amounts for items reclassified into this new subgroup increased by 100% from $40 to $80 for the 'Antimicrobial, Low Antigenicity, Micro-fibrous' suffix, and from $38 to $76 for the 'Antimicrobial, Low Antigenicity, Woven' suffix. Total usage for several of these items increased significantly . Consequently, total benefits for the '03.05.04.02 – Absorbable 51cm^2 – 75cm^2' subgroup increased from FY15 to FY16.

Finding 4.5.2

The examples in this section provide clear evidence of significant increases in benefit amounts for items in long-standing use that have not changed. In each case, usage increased following the increase in benefit amount.

4.5.3 Benefit amount relativity anomalies

Benefit amount differentials were identified between products which are not readily explainable by differences in the products themselves. This may suggest that the PL is also resulting in higher benefit amounts than would otherwise be expected. This can arise where products are reclassified to another related subgroup or suffix and achieve substantial increases in minimum benefit amounts without necessarily any changes in the product, as discussed in Section 4.5.2. Additionally, problems can also arise where products which are potentially substitutable have significantly different benefit amounts and so the absence of a price signal to the clinician means that higher volumes of the more expensive versions are being used than would otherwise be required.

4.5.3.1 Internal Adhesives

Significant differences in the minimum benefit amount per item for products in the '03.08.02.01 – Adhesive ≤2ml' subgroup of '03.08.02 – Internal Adhesives' were noted. Specifically, products within the 'Synthetic' suffix appear at two distinct benefit levels where, for the rest of the PL, typically benefit amounts do not differ between products in the same suffix grouping. The higher benefit level of $258 per item as at February 2020 represents a 514% higher benefit per item than the lower amount of $42.

It seems that this lower amount relates to the introduction of topical skin adhesive products to this part of the PL, with many of these products typically listed at the lower amount. There appear to be inconsistencies in which products are included at each benefit amount. It is therefore unclear how the significantly large differential in benefit amounts between these products is justified and whether the more expensive products are themselves associated with improved clinical effectiveness or patient outcomes. Moreover, these products are associated with significantly large (and growing) levels of usage. Further investigation of the evidence for the differences in benefit amounts for these products is required. A more detailed discussion of this is provided in the case study in Section 5.2.

4.5.3.2 Infusion Pumps, Balloon Based

High benefit amount differentials are observable for the various infusion pump products, particularly within the "03.02.02 – Infusion Pumps, Balloon Based" group. Products within this group range in minimum benefit amounts from $50 through to $450 and there was evidence of a strong preference in usage for the more expensive options within the variable flow rate subgroup. This could have been potentially driving substantially higher benefit amounts than might otherwise have been required to achieve the same required clinical outcomes.

Concerns regarding the large benefit differentials for these products were raised in consultation submissions. These submissions highlighted that the types of pumps are often interchangeable with the main differentiating factor between the variants being the inclusion of additional features to the product. Clinical subject matter resources and consultation submissions highlighted that these additional features may not be necessary for all cases in which they are used or may only drive minimal improvements in clinical effectiveness and patient outcomes. These products are discussed in further detail in case study 'Infusion Pumps' in Section 5.5.

4.5.3.3 Pliable Patches

Within the '03.05.04 – Pliable Patches' group, the amount of benefits paid per item used varied between three size variations and across four suffixes, as shown in Table 12 below.

Table 12 - Pliable patches – Comparison of minimum benefit amounts

	Suffix				'Microfibrous' relative to 'Standard'
Subgroup	**No suffix**	**Standard**	**Woven**	**Microfibrous**	
03.05.04.01 - Absorbable ≤50cm²	$8	$19	$33	$34	179%
03.05.04.02 - Absorbable 51 cm² – 75cm²	N/A	$19	$65	$69	363%
03.05.04.03 - Absorbable >75cm²	$26	$34	$91	$98	188%

It is noted that the relative difference in the benefit amounts per item between the more expensive 'Microfibrous' (Antimicrobial, Low Antigenicity, Microfibrous) and 'Woven' (Antimicrobial, Low Antigenicity, Woven) versions and the 'Standard' (Antimicrobial, Low Antigenicity) versions differed significantly for the middle size subgroup '03.05.04.02 - Absorbable 51 cm^2 – 75cm^2'. This was primarily due to the benefit amount for the 'Standard' version not varying between the smallest and middle-sized subgroups. At the same time, usage of the 'Standard' version for each subgroup differed. Consequently, the average benefit per item for the middle subgroup became the largest out of all three subgroups.

4.5.3.4 Matrix

Within the '03.05.05 – Matrix' group, there are a variety of benefit amounts for 'liquid' matrix products. These liquid matrix products are firstly divided into subgroups based on the volume of the product, and then further based on whether they fall into the 'Complete Biomaterial' suffix or not. The benefit amounts for these various combinations are shown in Table 13 below.

Table 13 – Matrix, 'Liquid' – Comparison of minimum benefit amounts

	Suffix	
Product subgroup	**No suffix**	**Complete Biomaterial**
03.05.05.01 - Liquid ≤6ml	$407	$632
03.05.05.02 - Liquid >6ml	N/A	$903

One product in this category has been the third largest single item contributing to growth in benefits for the 'High' priority GM category, increasing in annual benefits by $8.8m over FY14 through FY19.

There was a suggestion that the inclusion of Thrombin in some liquid Matrix products justified the listing of this product in the 'Complete Biomaterial' suffix. As a consequence, the benefit amounts for this suffix are higher than the no suffix counterparts.

It was suggested by consultation submissions and clinical subject matter resources that there is a lack of evidence supporting the clinical superiority of the use of Thrombin for patients not in low Thrombin states. Moreover, it was suggested that usage of Thrombin can even be associated with an increased chance of adverse outcomes, such as transmission of viral diseases, allergic reactions or development of antibodies. No conclusions are drawn as to the relative clinical effectiveness of these products on the basis of these comments; however, this may indicate that further investigation is required.

Finding 4.5.3

There have been a number of cases where the higher cost products were used more extensively than the lower cost alternatives, potentially increasing the total benefits for the PL. In many of these cases, the pricing relativities between products appear at odds with differences in their clinical functionality.

However, as noted in 0, it is difficult to determine whether the larger/more expensive versions of these items are warranted by clinical need or other efficiencies to drive better outcomes.

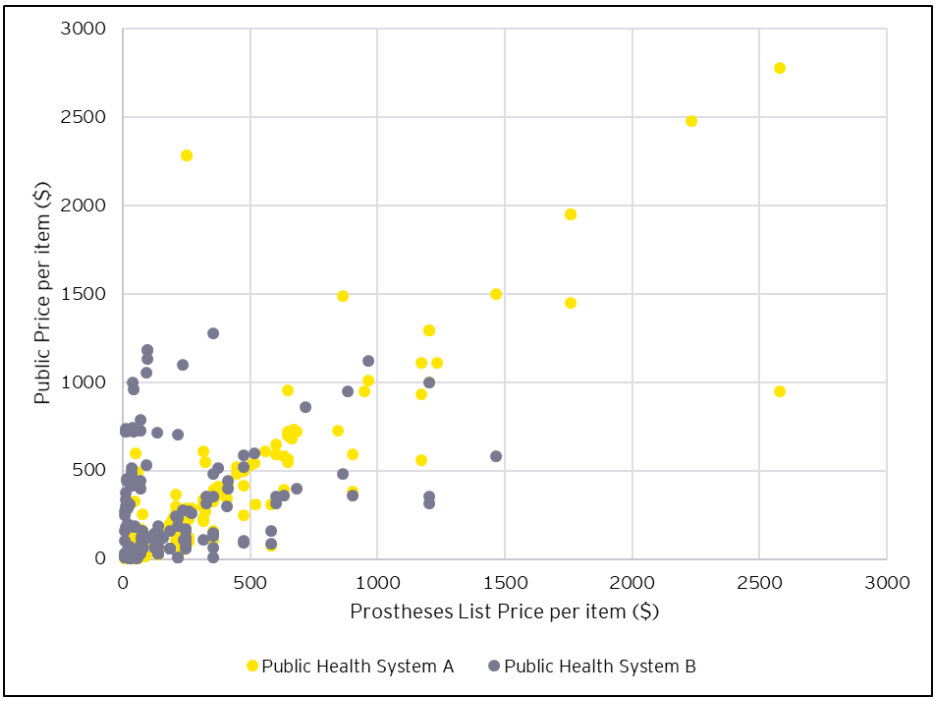
4.5.4 Comparison to the public system

If the PL is reducing the level of competition between medical device manufacturers, the benefit amounts on the list might be expected to be higher than those observed in the public system where

there is no PL equivalent funding mechanism. As such, prices for similar items were compared between the public and private system to assess whether this is observable for the PL.

However, it was observed that, generally for these types of GM items, public hospitals often used the PL as a benchmark when setting the prices which they will purchase items at. Evidence of this can be seen in Figure 23, which compares the public prices for two Australian jurisdictions with the PL minimum benefit amounts for all items in the GM category. It shows that many of the benchmarked items appear along the diagonal, representing close to a 1:1 relationship between the public hospital pricing and the PL. However, the chart also shows exceptions where the public hospital price was cheaper than the PL, and instances where the public hospital prices were more expensive.

Figure 23 – Benchmarking of GM PL item prices between public and private health systems



In general, cheaper public pricing generally occurred for lower cost items that were purchased in high volumes. These items are either high volume and fast-moving, or items where market share or volume commitment arrangements between the supplier and the public system have resulted in reductions in prices below either the PL minimum benefit amount, or the price normally offered by manufacturers to hospitals. Additional detail is included in Appendix C.

4.5.4.1 High volume and fast-moving items

An example of an item that is priced lower in the public system due to significant volumes in purchase orders was seen for a product within the 'Laparoscopic' suffix of the subgroup '03.08.03.03 - Clips with Disposable Applier'. In one of the public health systems analysed, this item accounts for 87% of the items purchased in the 'Laparoscopic' suffix between FY17 and FY19. Due to the high volume of items purchased by this public health system, the items were purchased at a saving of 69% compared to the minimum benefit amount on the PL.

4.5.4.2 Market share or volume commitments

A more common mechanism used by public health systems to achieve lower prices for items is to negotiate market share or volume commitment arrangements with the manufacturer. Health systems will commonly use a competitive tendering process to acquire items that are required. In

some cases, as part of this procurement process, a commitment relating to volumes or market share is made that results in lower prices being offered by the manufacturer for the product in question.

Items that were benchmarked in the group '03.05.02 – Powder' were found to be between 5% and 62% more expensive in the public health system when compared to the PL minimum benefit amount for those items. However, where a market share commitment was made for one powder product, the price for the public health system was lowered to a price 35% less than its PL minimum benefit amount.

In another example, one of the items under the 'Complex' suffix in the subgroup '03.08.01.04 - Gel/Liquid' was provided to one public health system at a 20% reduction on the PL minimum benefit amount, without any market share or volume commitment arrangements in place. If a hospital within that public health system was able to provide the vendor with a significant volume of market share in that product group, the price would further reduce by 10%.

Further evidence of volume-based discounting is shown with a product in the subgroup '03.02.05.02 – Administration Cassette'. In this case, out of all items benchmarked, this product accounts for 42% of the items purchased by a public health system in the subgroup. The one-off, non-committal prices offered to the public health system by the vendor for this item was similar to the minimum benefit amount for items in this subgroup on the PL. However, with an increased volume commitment from a hospital within this health system, the vendor discounted the price of the product by 56%. In this subgroup, another product from a separate vendor is also used by the public health system. Even without any volume commitments, this product is offered to the public health system at a price 58% lower than the minimum benefit amount on the PL.

4.5.4.3 Low volume items

The above examples all show that, when there are either high volumes or the possibility of high volumes or significant market share, manufacturers can offer products at a price that is lower than the minimum benefit amount of the item on the PL. Conversely, items with low volumes can experience more expensive pricing. For example, of all the items benchmarked, the group '03.05.03 – Sponges' appears to have very little usage in either of the public health systems analysed. For items in this group, the prices in the public system are generally more expensive than the minimum benefit amount on the PL. Within one of the public health systems, where 6 different items had some volume of product purchased, 5 out of the 6 items were more expensive in the public health system than the PL.

4.5.4.4 Overall findings

The benchmarking of the prices in two different Australian public health jurisdiction systems against the PL provided several key findings. Firstly, because of the competitive tendering process, if health systems can purchase a product in high volumes or can commit to purchasing a high volume of that product or providing a significant market share to a manufacturer for that product segment, then significant discounts can be achieved. This can result in the prices of items in the public health system being cheaper than the benefit amounts on the PL. However, items that are purchased in smaller volumes where volume commitments cannot be offered can be more expensive than the benefit amounts on the PL.

The implications from this is that where private hospital groups can either purchase items in a large quantity or provide a commitment to doing so, either because the private hospital group is large enough or because the item is used often enough in their private hospitals, the competitive tendering process along with volume commitments can result in significant discounts and savings for the private health system for these items. However, items that are purchased at smaller quantities

due to the private hospital being smaller, the item being used less often, or a combination of both can end up being more expensive without the PL to set a price. This could be particularly concerning for the viability and continued operation of smaller private hospitals and private hospital owners.

Additionally, it is important to note the importance of the PL in setting prices in the public health system. As seen in the diagonal line in Figure 23, public health systems rely heavily on the PL to help them set an expectation for the prices of different products. This means that the negotiations and discounts for different items in the public systems are still reliant on the price set on the PL as a benchmark and are therefore still not truly reflective of the 'market price' achievable for the product in an entirely competitive environment.

Finding 4.5.4

Overall, the analysis in this section does not suggest that GM items on the PL have significantly higher benefit prices than in the public system. For low volume products, the analysis found that the PL can provide a discount compared to the public sector. Conversely, for high volume products, like many GM items, the public sector can offer lower prices, especially where market share or volume commitments are agreed to. However, as the public health system relies heavily on the PL when setting prices, this analysis does not necessarily suggest that the PL is reflective of a true 'market price'.

4.6 Alternative funding mechanisms

The approach was to:

- collect feedback from stakeholders and input from the Department and clinical subject matter resources on the alternative funding mechanisms that exist; and
- analyse the usage of items since listing.

Items with potential usage and/or benefit amount issues identified in Sections 4.4 and 4.5 could then be candidates for considering alternative funding arrangements. Additional discussion on the benefits of the main alternative funding mechanism is given in Section 6.2.1.

This component and the discussion in Section 6.2.1 are intended to address the Terms of Reference items 3, 4 and 5.

4.6.1 Case based or bundled payments

The main alternative to funding these items through the PL would be for them to be included within case based or bundled payments, such as DRG based payments or banded theatre fees relating to the nature of the procedure being performed under the National Procedure Banding schedule. The precise mechanism by which insurers reimburse these fees would depend on the arrangements between insurers and hospitals. Theatre fees are intended to include consumables and disposable instruments.

The effect of removing these items from the PL and funding them in this way would be consistent with stakeholder feedback that observed that, for example, many items in the group '03.08.04 – Staples & Tackers' are disposable and consumable products.

Indeed, many of these items were previously funded in this way, including the items that have shown sudden increased usage since listing. As such, an element of the growth observed for these products represents a transfer in funding arrangements. Where the case based or bundled payments

were not explicitly reduced following the listing on the PL, it could be argued that the items are being doubly funded.

In other cases, PL-funded items are being used instead of items that perform similar clinical roles but are funded in this way. For example:

- There are other products that are similar or could serve as substitutes to items in the '03.05.05 – Matrix' group;
- Many internal adhesives in the '03.08.02 – Internal Adhesives' group are alternatives to sutures, which are explicitly excluded from the PL; and
- While some products were included on the PL a competitor's equivalent products were not.

The merits of this alternative funding mechanism for 'High' priority GM items, compared to the PL, is discussed in Section 6.2.1.

4.6.2 Eclipse funding

Stakeholders indicated that some items exist on the Eclipse system, a tool for Medicare Online claiming. In these scenarios, hospitals can claim funding for those products from private health insurers through in-hospital claiming arrangements. Items on Eclipse include some products in the '03.05.03 – Sponges' and '03.08.04 – Staples & Tackers' groups. However, it is suggested that most hospitals continue to charge for these items through the PL because it has a higher, non-negotiated price through this mechanism.

Finding 4.6

The main alternative to funding these items through the PL would be for them to be included within the case based or bundled payments.

5. Case studies

5.1 Introduction

In Section 4, the findings from the review of the 'High' priority GM items were discussed across a number of topics relating to areas where potentially adverse outcomes were being driven by the usage, pricing and categorisation of items in the GM category of the PL. In this section, a number of the examples outlined in Section 4 are presented as individual case studies to support this discussion. These case studies represent examples where there was a significant potential impact on total benefit amounts or where a number of different impacts were observed relating to specific items.

Table 14 lists the different case studies examined in the following subsections. For each case study, areas where significant issues or concerns are discussed are coloured in red, areas where some minor issues or concern are discussed are coloured in amber, and areas that have minor concerns noted but not discussed in detail are coloured in yellow.

Table 14 – Summary of case studies

No.	Case study	Meets listing criteria	Above trend usage	Significant benefits per item increases	Benefit amount relativity anomalies	Categorisation issues	Alternative funding mechanisms available	Price bench-marking	Page
1	Internal Adhesives								58
2	Staples and Tackers								61
3	Matrix								64
4	Infusion Pumps, Balloon based								65
5	Infusion Pump Accessories								66

5.2 Internal Adhesives

The internal adhesives group (03.08.02 – Internal Adhesives) is part of the closure devices subcategory (03.08 – Closure Devices) of the GM category. This product group encompasses surgical glues, sponges and patches that are used as sealants to prevent leakage of fluids and to control bleeding.

Large levels of growth were observed for the internal adhesives group. Notably, total annual benefits paid for this group grew at a CAGR of 28% from FY14 through to FY19. This had a particularly large impact on total benefits for the GM category as internal adhesives represented the second largest group of items in the 'High' priority GM category. As a result, total annual benefits increased by $30.5m from FY14 to account for almost $43m in benefits in FY19. This large pace of growth significantly outstripped the level of growth in separations over the same period (roughly 3% CAGR), suggesting that the growth may have been driven by factors other than pure clinical need.

5.2.1 Topical skin adhesives

It is apparent that a large amount of the observed growth was due to the introduction of topical skin adhesive products to this part of the PL. These products are typically used for the purposes of skin closure on the surface. Consultation submissions described topical skin adhesive products as representing alternatives to other skin closure techniques such as skin sutures, which are covered under general hospital payment methods.

Topical skin adhesive items were first introduced to the PL in February 2017 and subsequently expanded in 2018.

5.2.1.1 Usage

Figure 24 and Figure 25 show how much of the growth for internal adhesives occurred in the two years following the introduction of topical skin adhesives and within the subgroup under which these topical skin adhesives were listed (03.08.02.01 - Adhesive ≤2ml). In particular, in the two-year period from the end of FY17 to FY19 the total annual benefits paid for this subgroup increased by over $15.6m, a 527% total increase.

Figure 24 – Internal adhesives – Item usage by subgroup

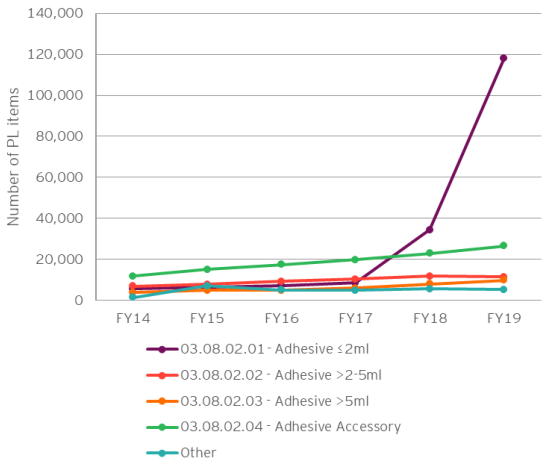
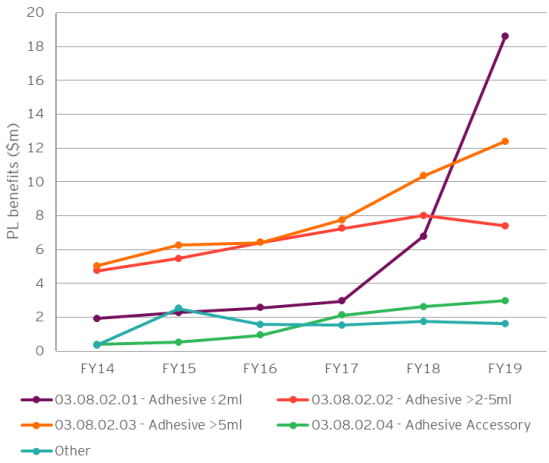


Figure 25 – Internal adhesives – Total PL benefits by subgroup



The addition of these products represented an apparent expansion of the types of products included on the PL and led to a rapid increase in usage (and hence benefits) for the PL. This was reflected in the large increase in usage (with respect of the PL) noted in a short time following their initial

availability on the PL. It was suggested in consultation submissions and from clinical subject matter resources that these products may not align with the intention of the PL and with the listing criteria themselves, as presented in the Prostheses List Guidelines. Alignment with the criteria is specifically discussed in greater detail in Section 4.3.2.

Furthermore, it is evident that the rate at which these topical skin adhesive products were used differed significantly between the various hospital groups. Particularly high rates of usage were seen for two large hospital groups, with one showing a rate of usage over 51% larger than that observed for another. The differences between usage across hospitals may be suggestive that the extent of usage of topical skin adhesives was at least partially been driven by factors outside of the clinical need. For example, a preference for these products over alternatives such as skin sutures might be expected to be less uniformly experienced across hospitals than if the use was driven by reasons of clinical need or outcomes. It may also be explainable by differences in case mix or other clinical factors between facilities themselves.

It is also evident from the consultation submissions and clinical subject matter resources that these products existed and were widely used for a number of years prior to their introduction to the PL but were funded through alternative arrangements. It is not apparent without further information if this growth was reflective purely of a transferral of usage between these funding sources and therefore whether a greater level of usage was driven by their inclusion on the PL. However, the substantial increase in benefits that this set of products represented in a short period of time indicates that further investigation is warranted.

5.2.1.2 Minimum benefit amounts

That the inclusion of topical skin adhesive products represents an expansion of the PL, rather than new versions of similar products that already existing on the PL, is further suggested by the apparent discrepancies in minimum benefit amounts between many of these products and other internal adhesives.

The lowest level at which minimum benefit amounts are typically set is by suffixes within subgroups, with all products belonging to the same suffix-subgroup 'cell' sharing the same minimum benefit amount. For the '03.08.02.01 - Adhesive ≤2ml' subgroup, however, products within the 'Synthetic' suffix are further listed at two distinct and significantly different benefit levels. In particular, as at February 2020 most products were listed at $258 per item, which was 514% higher than the lower amount in the same suffix of $42 per item. The various minimum benefit amounts for these products are outlined in Table 15 below.

Table 15 – Internal Adhesives – Summary of minimum benefit amounts by subgroup and suffix

	Suffix		
Subgroup	**Synthetic**		**Biological**
03.08.02.01 – Adhesive ≤2ml	*Low amount* $42	*High amount* $258	$327
03.08.02.02 – Adhesive >2-5ml	$516		$602
03.08.02.03 – Adhesive >5ml	$963		$1,204

It is apparent that this lower benefit level may have been intended for these topical skin adhesive products, as it first appeared on the PL when one product was reduced to $45 per item after initially being listed at the standard amount of $300. Subsequently, new internal adhesive products were typically listed at this new, lower amount.

This appears to be somewhat inconsistent, however, with some products described as topical skin adhesives listed at the higher amount of $258 instead.

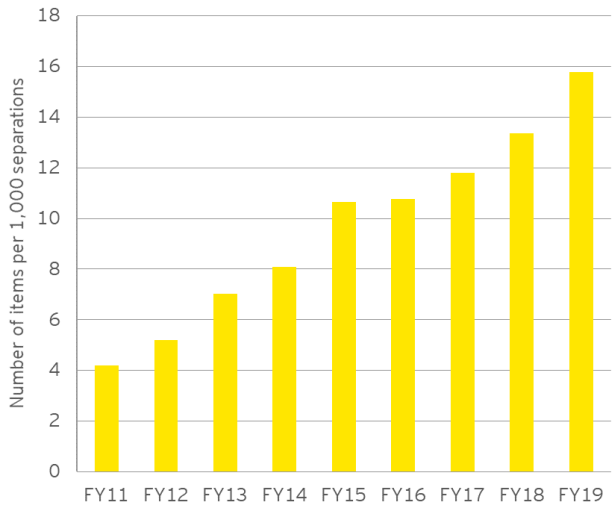
It is unclear as to the basis by which a product is listed at either price and whether the large differential in benefit amounts between these various products reflects differences in clinical effectiveness or patient outcomes. Moreover, these products were associated with significantly large (and growing) levels of usage.

5.2.2 Other internal adhesives

There was also significant growth in the usage of internal adhesives outside of the topical skin adhesive products. Since FY11, total benefits for internal adhesives when excluding topical skin adhesives grew at a 21% CAGR, increasing from over $720k annually in FY11 to over $3.3m in FY19.

Adjusting for growth in separations over the same period, this corresponded to a 16% CAGR in total annual benefits for these items. As is evident from Figure 26, this was driven by growth in the rate of usage of these products per separation over time, which grew at an overall CAGR of 18% over the same period. This indicates that the growth in usage was significantly in excess of the growth in surgical procedures over the same time period.

Figure 26 – Internal Adhesives (excl. topical skin adhesives) – Items per 1,000 separations



The largest contributors to growth in usage for internal adhesives in terms of type of procedures was general surgical and bariatric surgery procedures, as shown in Figure 27. Bariatric procedures were separated as a distinct sub-grouping within general surgical operations at the start of FY14. Combined, these two types of procedures accounted for 51% of the growth in usage since FY11 with usage per separation growing at a 23% CAGR. Since establishment in FY14, usage per separation for bariatric procedures gew at an 8% CAGR and general surgical (excluding bariatric) at 16% CAGR.

This large annual growth was also observed generally across a range of other procedures. In particular, as shown in Figure 28, significant rates of growth in usage were observed for both orthopaedic and gynaecological procedures. In FY11, these two types of procedures combined accounted for 7% of all items used from the internal adhesives group, which increased to 20% by F19.

The high level of growth seen across a wide variety of types of procedures shows that the rate of usage of internal adhesive products grew significantly faster than general levels of growth in surgical

procedures and was not specific to advancements in any one type of procedure. This may be suggestive that the availability of these products on the PL was driving levels of usage beyond clinical needs.

Figure 27 – Internal Adhesives (excl. topical skin adhesives) – Number of items used by type of procedure

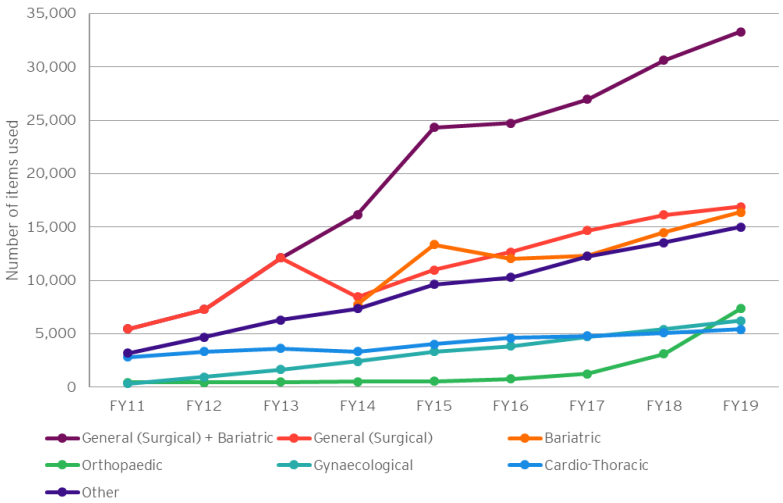
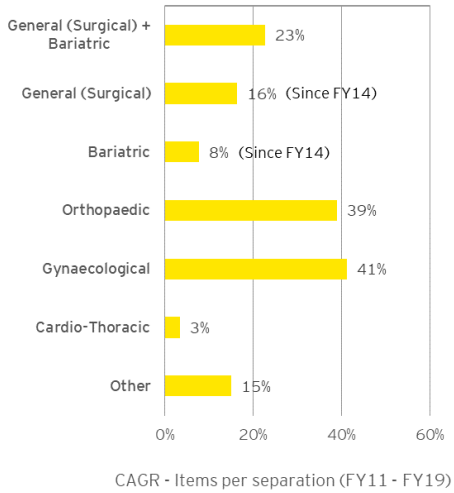


Figure 28 – Internal Adhesives (excl. TSA) – CAGR, items per separation (FY11 – FY19), by grouping of primary MBS code



Additionally, within the '03.08.02 – Internal Adhesives' group, there were significant differences in the rate of item usage per separation between the larger hospital groups and the smaller hospital groups. Specifically, it is apparent that the larger hospital groups were using these items at a significantly higher rate than the smaller hospital groups. The large increase in usage seen in FY18 and F19 was due to the introduction of topical skin adhesives. The differences seen in the usage rates between hospitals groups may indicate a preference to use internal adhesives over alternative products, or for internal adhesives to be used in greater volumes. It may also be explainable (at least partially) by differences in case mix or other clinical factors between facilities themselves.

5.3 Staples and Tackers

The '03.08.04 – Staples and Tackers' group constituted the single largest group in the GM category of the PL as it accounted for almost $96m in benefits or almost 43% of all benefits for 'High' priority GM in FY19. Annual benefits for this group grew by over $39m in the period from FY14 through FY19, representing an 11% CAGR over the same period. This product group encompasses specialised staples used in surgery in place of sutures to close wounds or connect tissues. Staples are also used extensively in bowel, gastric, gynaecological and thoracic surgical stapling procedures.

Of the top 10 individual items contributing to growth in benefits for the 'High' priority GM category, 6 were from the staples and tackers group. Significant trends of growth in benefit amounts were noted across many of the group's subgroups as is evident in Figure 29 and Figure 30. Accordingly, staples and tackers represented a group of significant interest for this review. This case study provides further detail on patterns of usage and benefits across a number of different areas within the staples and tackers group.

Figure 29 – Staples & Tackers – Total PL benefits by subgroup

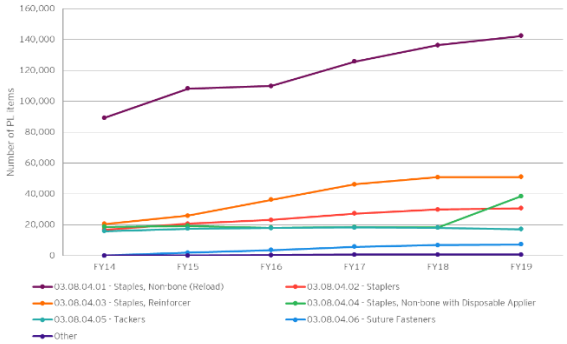
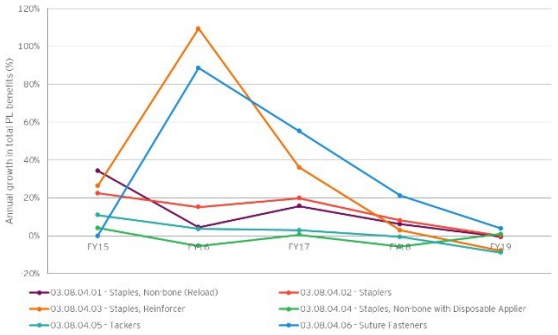


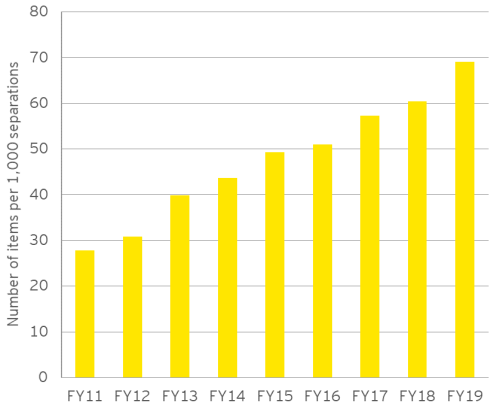
Figure 30 – Staples & Tackers – Annual growth in benefits by subgroup



5.3.1 Overall high rates of growth

Usage per separation for the staples and tackers group increased steadily from FY11, as indicated in Figure 31, at a CAGR of 12%. Consultation submissions and clinical subject matter resources highlighted that recent shifts and advancements in clinical practice towards keyhole surgery over open surgery resulted in a greater need for use of these items in related procedures and may have been a key contributor to this growth. However, it was also noted from these submissions that there is significant scope for increased usage or wastage of these items beyond pure clinical need, for example through overuse of staple reloads than might otherwise be required.

Figure 31 – Staples & Tackers – Items per 1,000 separations



The growth observed in usage per separation was primarily driven by usage of these products in general surgical and bariatric surgery procedures. At the start of FY14, bariatric surgery procedures were established as a distinct subgroup of general surgical procedures on the MBS. Looking at bariatric and general surgical procedures combined, the growth in their usage accounted for 75% of the total growth in usage for the staples and tackers group.

Growth in usage of these products for bariatric surgery significantly outstripped growth in the number of these procedures at a rate of 8% p.a. (CAGR) from FY14, as shown in Figure 33. A similar rate of growth of 7% p.a. was seen for the wider general surgical procedures (excluding bariatric surgery). High growth was also observed in the cardio-thoracic and orthopaedic surgical categories, and more generally across a wide range of procedures. The particularly high growth observed for orthopaedic surgical procedures was primarily due to the introduction of a single product.

Figure 32 – Staples & Tackers – Number of items by grouping of primary MBS code

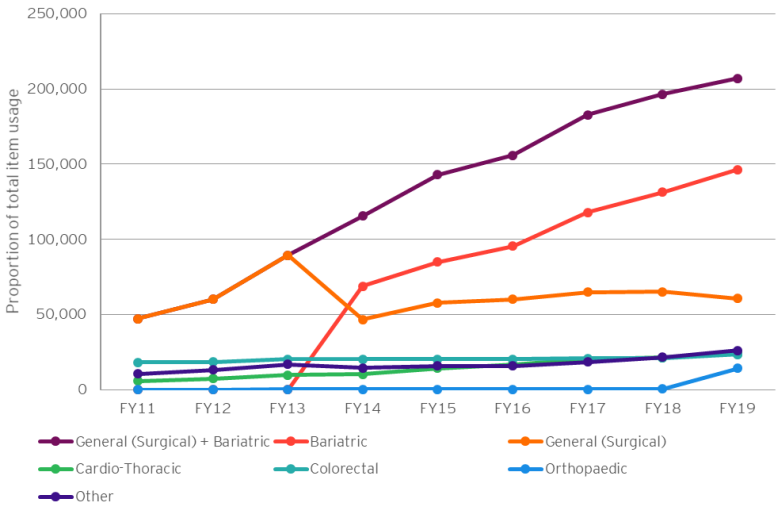
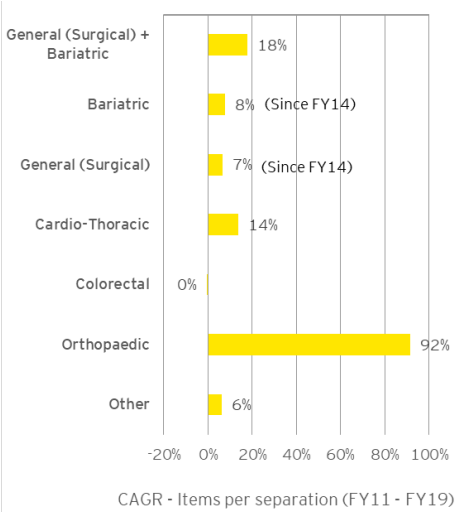


Figure 33 – Staples & Tackers – CAGR, items per separation (FY11 – FY19), by grouping of primary MBS code



Whilst a shift in clinical practice relating to bariatric surgery was a big driver of the growth in the use of these items, there was also an increased usage at a separation level. Furthermore, significant growth was also seen outside of bariatric surgery, meaning this alone does not explain the entire extent of growth.

Growth was not uniformly experienced across the various hospital groups investigated. In particular, the two large hospital groups experienced rates of growth significantly in excess of smaller hospital groups. Notably, annual benefits for one hospital group increased by 284% over the 5 years, or 18% CAGR, significantly greater than any others. The large difference in these rates of growth may be suggestive that factors outside of clinical needs may influence the usage of these products.

5.3.2 Staples, Non-bone (Reload)

The '03.08.04.01 – Staples, Non-bone (Reload)' subgroup accounted for half of all PL benefits paid for the '03.08.04 – Staples & Tackers' group in FY19 ($48m). Within this subgroup, at the suffix level, there was an increasing trend in the level of item usage for the more expensive 'Endoscopic, Articulating/Roticulating' versions (with a minimum benefit amount of $323 as at February 2020). At the same time, there was also a notable decreasing trend in the level of item usage for the less expensive versions without a suffix (with a minimum benefit amount of $210 as at February 2020).

The growth was primarily driven by two main products, which were in the Top 10 contributors to growth for the GM category overall. These two products were associated with an increase in annual benefits of $14.4m and $7.5m from FY14 to FY19 respectively, or $21.9m in aggregate. It is further noted that there were some further offsetting decreases in other products not factored into these figures with annual benefits for the subgroup increasing by $20m over the same period in aggregate.

These products provide an example where the more expensive products in a subgroup were used more extensively than the cheaper alternatives. Investigation is required to determine whether this usage is appropriate and providing better clinical outcomes or whether this is an example of the PL not disincentivising the choice of items that are more expensive than other clinically sufficient items.

5.3.3 Staples, Non-bone with Disposable Applier

The 'no suffix' suffix grouping in the subgroup '03.08.04.04 – Staples, Non-bone with Disposable Applier' experienced significant growth in item usage in FY19, along with an increase in the PL benefits paid for this suffix. Usage grew by over 20,000 items, representing a 172% increase from FY18, mostly driven by one item.

5.4 Matrix

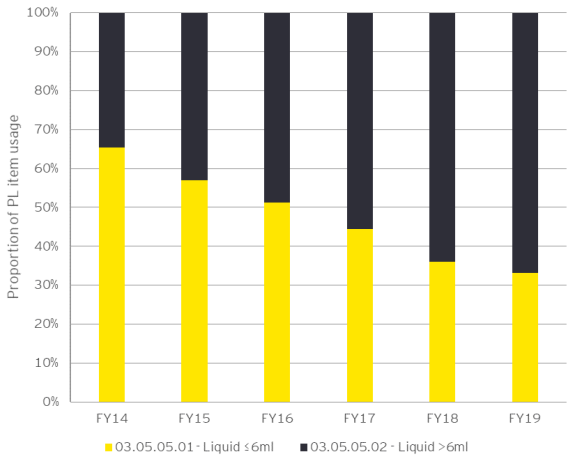
The matrix product group (03.05.05 – Matrix) is part of the haemostatic devices subcategory (03.05 – Haemostatic Devices) of the GM category. These products include high viscosity gels used for achieving haemostasis that are typically delivered through a syringe when control of bleeding by ligature or conventional surgical procedures is ineffective or impractical. Matrices in a liquid form dominate this category but there are also non-liquid and powder versions available.

5.4.1 Liquid matrix products

Growth in benefits for the '03.05.05 – Matrix' group was driven primarily by the '03.05.05.02 - Liquid >6ml' subgroup. This subgroup also represented the most expensive products in the matrix group at an average benefit amount of $950 per item, almost 49% higher than the smaller volume liquid matrix products '03.05.05.01 - Liquid ≤6ml' at an average benefit amount of $640 per item.

There were different usage patterns observed between the two sized options of liquid matrices, with a significant trend towards greater usage of the larger volume items over the period from FY14 through FY19. This was a consequence of high rates of growth in item usage for the larger volume while usage for the smaller volume remained comparatively constant, despite the significant price differential between these two sets of products. Where this usage of a larger volume was not necessarily required, this led to wastage and contributed to greater benefits being paid than might otherwise have been needed.

Figure 34 – Matrix, liquid – Proportion of total PL item usage



The apparent preference for the larger volume products was seen generally across the board for private hospital groups. The proportion of use of this large volume subgroup increased across the majority of hospital groups since FY11.

However, the apparent preference for the larger, more expensive volumes was not replicated for private patients in public hospitals. In particular, usage of the large volume only made up 27% of total liquid matrix usage in FY19 for private treatment in public hospitals, significantly smaller than

the 68% average across all private hospitals. Clinical subject matter resources suggested that there is not an obvious reason why private treatment in public hospitals would clinically require smaller sizes than would be required in private hospitals. As a result, these observed differences may be suggestive that the increased preference for larger volumes observed within private facilities may not strictly have been driven by clinical need alone.

5.5 Infusion Pumps

Infusion pumps represented $10.9m in benefits paid in FY19 across three product groups: '03.02.02 – Infusion Pumps, Balloon Based', '03.02.03 – Infusion Pumps, Battery Powered' and '03.02.04 – Infusion Pumps, Spring Powered'. These product groups encompass single-use, portable infusion pumps for patients that provide liquid medication at a continuous flow rate over a specified period. These devices are intended for the infusion of antibiotic therapy, chemotherapy, pain management, and other infusions administered via intravenous, intra-arterial, subcutaneous or epidural methods.

In Section 4.3.2.2 there is a detailed discussion on the eligibility of infusion pumps for inclusion on the PL that concludes that the case that they meet the criteria for listing is tenuous at best.

5.5.1 Differential usage by hospital owners

There was differential usage between hospital groups for infusion pumps across the three infusion pump groups (03.02.02, 03.02.03 and 03.02.04). The overall usage of infusion pumps per separation, was significantly higher for two private hospital groups compared to others.

At the group level, there appears to have been a substitution effect occurring between '03.02.02 – Infusion Pumps, Balloon Based' and '03.02.04 – Infusion Pumps, Spring Powered' for some private hospital groups, with usage of the 'Spring Powered' infusion pumps decreasing at the same time that an increase in usage occurred for the 'Balloon Based' pumps.

There is evidence that some private hospital owners prefer the usage of '03.02.03 – Infusion Pumps, Battery Powered' compared to others, whereby increased usage of the 'Battery Powered' pumps appears to partially replace their previous usage of the 'Spring Powered' infusion pumps.

These significant differences in usage levels for infusion pumps suggests that their usage was not being driven purely by clinical need but, potentially, by clinician preferences and hospital contracting arrangements with manufacturers.

Furthermore, stakeholder feedback suggested that in some hospitals infusion pumps are being purchased through the PL and being returned to the hospital's capital equipment stock to be used for inpatients, which would lead to differences in recorded usage between hospitals. This would not be permitted under the Prostheses List Guidelines.

5.5.2 Infusion Pumps, Balloon Based

5.5.2.1 Usage

Usage of these types of infusion pumps grew significantly from FY14, primarily driven by large increases in FY15 and FY16 as is evident in Figure 36. However, this was reflective of an apparent shift in usage away from spring-powered infusion pump alternatives to these balloon-based versions, as suggested by the offsetting and simultaneous trends seen for both of these product groups in Figure 37.

Inputs from clinical subject matter resources indicated that this is reflective of the benefits provided by these balloon-based infusion pumps over the older-style spring-powered pumps, such as improved patient mobility.

Figure 35 – Infusion Pumps, Balloon Based – Item usage by subgroup

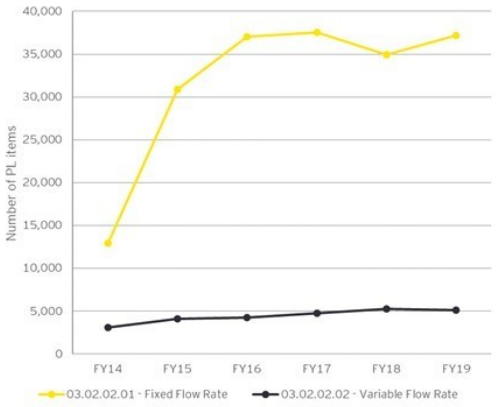
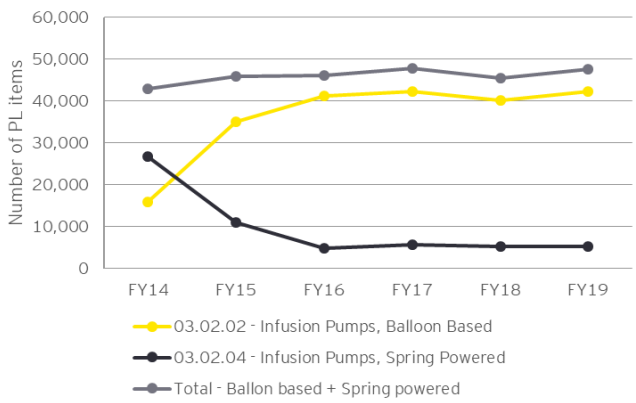


Figure 36 – Infusion Pumps – Usage of balloon-based and spring-powered pumps



Considering the offsetting impacts of these two trends, it is apparent that growth in benefits for the two product groups combined was minimal from FY14, corresponding to a 2% CAGR over FY14 to FY19. This reflected a slight decrease over the same period when adjusting for growth in the number of overall separations over this time, corresponding to a -1% CAGR in benefits per separation.

5.5.2.2 Minimum benefit amounts

Noting from above that growth in benefits for this group was minimal from FY16 (and in fact slightly negative after adjusting for the number of separations), concerns were raised in consultation and from clinical subject matter resources regarding the benefit amounts payable for some of these products. In particular, the range of minimum benefit amounts between many of these products was cited as potentially driving higher total benefits than might otherwise be necessary (i.e. where more expensive products are being used when the cheaper versions might be sufficient to achieve the same clinical outcomes).

The potential for this is apparent when looking at the range of minimum benefit amounts payable between the various types of infusion pump products, as illustrated in Figure 38. Notably, within the fixed flow rate versions, the 'Set' suffix products' benefit amounts are 207% more than the standard 'no suffix' versions. In addition, the variable flow rate 'Set' and 'Bolus' versions' benefit amounts are 127% and 173% more than the 'no suffix' versions, respectively. As shown in Figure 39, usage of these pumps was higher for the more expensive 'Set' and 'Bolus' products, compared to the predominant usage of 'No suffix' within the fixed flow rate subgroup.

Clinical subject matter resources and consultation submissions also highlighted that the types of pumps are often interchangeable, and that the additional features reflected by the different suffix groupings may not always be clinically necessary and/or may only be driving minimal improvements in clinical effectiveness and patient outcomes relative to the benefit differentials.

Figure 37 – Infusion Pumps, Balloon Based – Minimum benefit amounts by subgroup and suffix (as at February 2020)

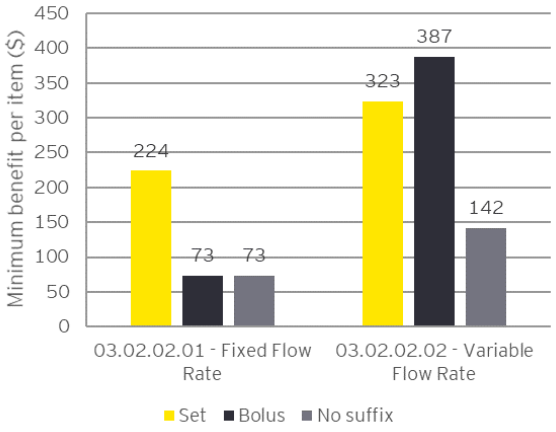
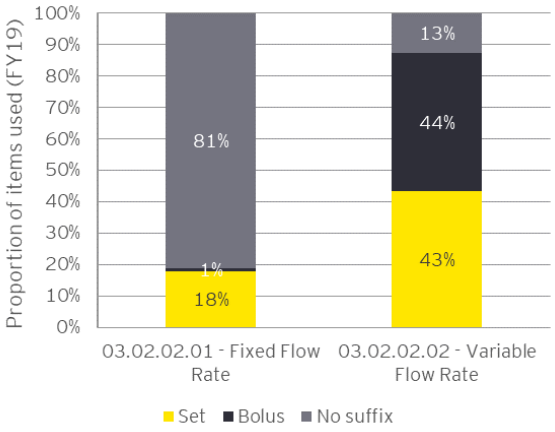


Figure 38 – Infusion Pumps, Balloon Based – Proportion of item usage by suffix for each subgroup



5.5.2.3 Large increases to benefit amounts

Concerns regarding the large differentials in benefit amounts between versions highlighted above are further supported by recent reclassifications of some fixed flow rate balloon-based infusion pump products into the "Set" suffix having previously been listed with no suffix. As a consequence of this reclassification, the minimum benefit amount for these products increased by 205% at the time of the change, increasing from $79 per item to $241 per item. This represented a 207% increase at February 2020 benefit amounts.

Due to the relatively recent nature of the changes, data is not available on any potential impacts on usage for these items. It is not evident if changes were made to the product itself as part of this reclassification. However, the extent of this sudden increase in benefit amount is such that it seems unlikely that any changes to the product would lead to improvements in clinical effectiveness or patient outcomes of a commensurate size.

6. Findings and next steps

The findings have been grouped into issues and then the causes of those issues. A summary of the next steps, including recommendations, for consideration by the Department is then provided.

6.1 Findings

6.1.1 Issues

Issue type	Finding	Relevant items on PL
Listing criteria	**Items not meeting the criteria** - reference 4.3.2 (1) There are specific examples on the PL that can be considered as not meeting the criteria for listing.	**03.08.02 Internal Adhesives** (topical skin adhesives) **03.02 Drug Delivery Devices**
	Range of items meeting the criteria - reference 4.3.2 (2) There has been an expansion in the nature of items being included on the PL. There is now a spectrum of items on the PL: from items that are clearly implanted prosthetic items through to items that are not strictly implanted themselves and/or are general use items that do not directly address the reason for surgery, and a range of items in between. This has resulted in items on the PL that arguably meet the criteria but that are potentially at odds with the purpose of the PL.	**03.05 Haemostatic Devices** **03.08 Closure Devices**
Usage	**Growth issues** *Overall growth* - reference 4.4.1 The 'High' priority GM items experienced 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. *Growth in usage per separation* – reference 4.4.4 There have been a number of examples of above-trend usage growth that can't be explained by increases in the number of procedures. In all cases, the level of growth was such that it seems unlikely that changes in the nature of procedures or in the case mix are sufficient to explain all of the growth. This suggests that at least some of the growth must have been due to an increase in the number of items per separation within the same procedures.	**Top 10 items** **03.08.04 Staples & Tackers** **03.08.02 Internal Adhesives** **03.02.03 Infusion pumps** (in particular 03.02.03.05) **03.05.02 Powder**

Issue type	Finding	Relevant items on PL
	This suggests that there was some element of over-use occurring in these groups. *High growth since listing* – reference 4.4.2 There are a number of items which have experienced significant and sustained growth in their usage since being listed.	**03.05.05 Matrix**
	Usage skewed towards more expensive options - reference 0 (1) There are numerous groups in which similar items differing by a characteristic (such as size) have different minimum benefit amounts. In some cases, the usage of these items differed significantly, and was skewed towards usage of the more expensive items, such as the larger versions of matrices, pliable patches, and some internal adhesives. Additionally, within the larger >75cm^2 pliable patches, PL benefits paid for the more expensive micro-fibrous version were higher than benefits paid for the cheaper Standard version. It is likely that in many cases usage of the more expensive option is more than sufficient to meet clinical needs and is therefore not the most efficient option from an overall healthcare costs perspective.	**03.05.05 Matrix** **03.05.04 Pliable Patches** **03.08.02 Internal Adhesives**
	Usage skewed to items that are listed on PL over comparable items not on PL – reference from 4.3.2 (3) and 4.4.2 Similarly to the above issue, there have been a number of situations where there was relatively high usage and/or high growth in usage of items on the PL where other, cheaper but clinically similar, products were available that are not on the PL. Examples of non-PL listed items that could have been used in place of PL listed items include: sutures; and other products that are similar or could serve as substitutes to items in the '03.05.05 – Matrix' group.	**03.05.05 – Matrix** **03.08.02 Internal Adhesives** **03.08.04 Staples & Tackers**
	Use of accessories with infusion pumps – reference 0 (2) There have been a number of examples where the use of an infusion pump accessory did not align with the use of the pump itself. This may be indicative of: • more accessories being used than clinically needed; • accessories being used for purposes not specified by their listing; or • the pump being reused after their initial purchase from the PL.	**03.02.05 Infusion Pump Accessories**

Issue type	Finding	Relevant items on PL
	Differences in usage between hospitals – reference 4.4.5 As discussed in Section 4.4.5, there is evidence of significant differences in growth and usage of some items between hospital groups. Whilst some of this was undoubtedly driven by differences in procedures and case mix between hospitals, it also suggests that hospital contracting arrangements and hospital and clinician preferences may have been having an impact on usage of these items.	**03.02 Drug Delivery Devices** **03.05 Haemostatic Devices** **03.08 Closure Devices**
Benefit amount	**Benefit amount issues** *Benefit amount increases not leading to reduced usage* – reference 4.5.2 The examples in this section provide clear evidence of significant increases in benefit amounts for items in long-standing use that have not changed. In each case, usage increased following the increase in benefit amount. *Benefit amount relativity anomalies* – reference 4.5.3 There have been a number of cases where the higher cost products were used more extensively than the lower cost alternatives, potentially increasing the total benefits for the PL. In many of these cases, the pricing relativities between products appeared at odds with differences in their clinical functionality. As noted in Finding 0 (1), it is difficult to determine whether the larger/more expensive versions of these items are warranted by clinical need or other efficiencies to drive better outcomes.	**03.08.02 Internal Adhesives** (adhesive accessories and adhesives ≤2ml) **03.02.02.01 Infusion Pumps, Balloon Based** **03.05.04 Pliable Patches** **03.05.05 Matrix**
	Comparison to the public system – reference 4.5.4 Overall, the analysis in Section 4.5.4 does not suggest that GM items on the PL have significantly higher benefit prices than in the public system. For low volume products, the analysis found that the PL can provide a discount compared to the public sector. Conversely, for high volume products, like many GM items, the public sector can offer lower prices. However, as the public health system relies heavily on the PL when setting prices, this analysis does not necessarily suggest that the PL is reflective of a true 'market price'.	**All 'High' priority GM items**

6.1.2 Causes

Cause type	Finding	Relevant effects/issues
Listing processes	**Lack of a robust assessment process for inclusion on the PL** That items have been listed on the PL but do not meet the criteria strongly suggests that there are issues with the inclusion assessment process. As noted in Section 4.3.2.6, the application assessment is often performed by individual clinicians with a focus on the absolute clinical benefits of the product – rather than a robust assessment of the extent to which the product meets the criteria and whether more appropriate funding mechanisms might exist.	4.3.2 (1)
	Ease of changing classifications The classification and listing processes have sufficient room for interpretation to enable items to be easily moved from one suffix to another, sometimes along with significant increases in benefit amounts. It should be relatively unusual to see a significant increase in the benefit amount for an item of long-standing use when there has been no change to the item itself.	4.5.2
	Lack of rigorous monitoring and enforcement The potential issues around inappropriate usage of infusion pump accessories would be a symptom of a broader issue relating to the lack of transparency (to the Department and to funders – private health insurers) around the circumstances of their use and the limited ability for usage that contravenes the Prostheses List Guidelines to be prevented or penalised.	0 (2)
Listing criteria	**Lack of clarity in listing criteria** There are a number of grey areas around the boundary for inclusion under criterion 4a. Specific issues arise from: • The lack of a clear definition for a 'prosthetic' item; • Ambiguity in the term 'implantable' – in particular, whether this should be long-term/permanent; and • Ambiguity in the terms 'pathological process' and 'physiological process' – for example, whether these include processes such as bleeding which can result from the surgery itself but are not the main reason for the surgery in the first place. Similarly, criteria 4b and 4c are open to interpretation since they do not require an explicit link to implantable devices to be specified, nor the extent to which it aids or continues to be critical to the implantable device. This highlights again the broad applicability of the listing criteria in their current form and the confusion around what constitutes a 'prosthetic' item. This can result in significant scope for inclusion of products that may	4.3.2 (2)

Cause type	Finding	Relevant effects/issues
	or may have been intended to be covered by the specific funding mechanism of the PL. Choosing a fairly broad definition for a prosthetic item, as has been done in the listing criteria, only makes it more difficult to precisely define boundaries.	
PL as a funding mechanism	**Inefficiencies from guaranteed itemised funding** The above problems with the PL would not necessarily cause issues if they did not lead to inefficient healthcare costs. However, the funding mechanism has implications for the commercial interests of key stakeholders including manufacturers, private hospitals and private health insurers. Higher usage and benefit amounts favour manufacturers over other stakeholders. Evidence for this includes: • High levels of usage – including increased usage since listing (discussed in Section 4.4); • Cases where benefit amounts have increased significantly with no reduction in usage (discussed in Section 4.5); • That more expensive products can sell more easily than cheaper products (see Section 0); and • An example where a manufacturer sought the removal of a competitor's product from the PL as its listing was giving the competitor a commercial advantage.	**Usage and Benefit amount issues** **4.3.2 (3)**
	Root causes of inefficiencies There is a clear separation between the guaranteed funder of GM items (insurers), the chooser of the items (clinicians) and the provider of the items (private hospitals). This means that the value of the items is not a direct consideration when selecting which (and how many) GM items should be used in a procedure – i.e. there is no disincentive to the clinician to use more items of higher cost, even if the clinical benefit of doing so is negligible. Whilst this can be argued for all items on the PL, it is particularly true for GM items because: • They are available at a range of price points (due to, for example, varying sizes or additional features); • They are often of low cost and so the marginal impact of additional use is minimal; and/or	

Cause type	Finding	Relevant effects/issues
	• Multiple quantities of the item can be used in a single procedure and so there is no natural upper limit to how many could be used (as opposed to, say, a prosthetic hip).	

6.2 Next steps

The findings in Section 6.1 show that there are a number of fundamental problems with using the PL to fund general use items currently listed in the following parts of the PL:

- 03.02 Drug Delivery Devices;
- 03.05 Haemostatic Devices;
- 03.08 Closure Devices, specifically:
    - 03.08.01 Adhesion Barriers;
    - 03.08.02 Internal Adhesives;
    - 03.08.03 Ligating Devices;
    - 03.08.04 Staples & Tackers;
    - 03.08.05 Polypropylene/Polyester Mesh; and
    - 03.08.11 Dynamic Wound Closure Devices.

The recommendations below focus on directly addressing these problems. However, it is possible that broader changes to the way that the overall PL works might either indirectly address these problems or make these receommendations ineffective. As such, it is important that these recommendations should be considered in the context of any potential other changes to the PL.

It is also worth noting that, while these recommendations only apply to the above items, there may be other non-GM categories with similar issues. As such, the overall consistency of the PL should be considered prior to any recommendations being implemented.

6.2.1 Recommendations

Recommendation 1: remove the 'High' priority GM items from the PL

The following groups of items should be transitioned away from the PL and instead funded through case based or bundled fee arrangements:

- 03.02 Drug Delivery Devices;
- 03.05 Haemostatic Devices;
- 03.08 Closure Devices, specifically:
    - 03.08.01 Adhesion Barriers;

- 03.08.02 Internal Adhesives;
- 03.08.03 Ligating Devices;
- 03.08.04 Staples & Tackers;
- 03.08.05 Polypropylene/Polyester Mesh; and
- 03.08.11 Dynamic Wound Closure Devices.

As described in Section 4.6.1, the main alternative to funding these items through the PL would be for them to be included within case based or bundled payments, such as DRG based payments or banded theatre fees relating to the nature of the procedure being performed under the National Procedure Banding schedule . The precise mechanism by which insurers reimburse these fees would depend on the arrangements between insurers and hospitals. Clearly, the specifications and associated prices relating to the case based or bundled payments would need to be reviewed and updated to reflect their increased scope. This is discussed further in the transition considerations in Section 6.2.2 below.

It would need to be considered whether items that can be funded through Eclipse should be included in the increased scope of case based or bundled payments.

The recommendation that this alternative funding mechanism be used for these items is made for reasons of efficiency, consistency and feasibility.

There is no suggestion that any of these items do not serve a clinical purpose in providing for optimal patient outcomes. As such, the transition considerations discussed in Section 6.2.2 should be considered in order to avoid unintended consequences.

Efficiency

Theatre fees are intended to cover consumables, disposable instruments and a contribution towards building and equipment costs. Including these items within such a group of costs and setting an overall single price for the group of costs that is related to the overall procedure is conceptually similar to Activity-based Funding (ABF) for public hospital services.

The efficiency benefits that ABF enables in the public hospital setting are well documented and arise because of the resulting cost-risk sharing between the hospitals, clinicians and funders. The Independent Hospital Pricing Authority (IHPA) has found that ABF "provides a powerful incentive for hospitals to perform as efficiently as possible"[9] and has been successfully driving improved efficiency by transitioning towards ABF for public hospitals. This was based on earlier findings of the National Health and Hospitals Reform Commission (NHHRC) relating to both public and private hospitals, which recommended "the use of 'activity-based funding' for both public and private hospitals using casemix classifications".[10]

In the private hospital setting, there are similar case mix funding arrangements between hospitals and insurers. However, it is important to acknowledge that, in this setting, the cost-risk sharing dynamics are less immediate because the hospitals have limited control over clinicians' choices in

[9] Activity based funding for Australian public hospitals: Towards a pricing framework (Independent Hospital Pricing Authority, 21 December 2011)

[10] A healthier future for all Australians (National Health and Hospitals Reform Commission, June 2009)

the operating theatre, and hospitals and clinicians do not have the same financial incentives driven by a shared profit bottom line. For efficiency benefits to be realised, hospitals would need to proactively engage with their clinicians regarding procurement and usage of the items.

Clinicians' choices of which general items should be used in surgery are typically driven by:

- **Quality:** product specification and efficacy based on output data literature evidence;
- **Service:** support offered by supplier representatives and the security of the supply;
- **Training:** educational materials and/or training courses provided; and
- **Familiarisation:** knowledge of the product based on experience or marketing.

Funding general items through case based or bundled payments would incentivise the hospitals to consider the cost of these items, as well as the above four points, in deciding which items it should stock. The hospital would therefore want clinicians' choices in surgery to be based on an aligned set of five (i.e. including cost) considerations.

The hospital could go some way to achieving this through a range of measures, including:

- Ensuring a transparent procurement process that directly involves its clinicians in the decisions made;
- Collecting and disseminating evidence on the clinical value and cost effectiveness of the items purchased;
- Monitoring usage, particularly of higher-cost items, and reassessing/intervening if usage is significantly higher than expected; and
- Developing processes that send a signal to clinicians to consider cost effectiveness – for example, enhanced approval processes prior to the usage of higher-cost items.

As well as cost-risk sharing incentivising efficiency, there is reduced administrative burden to hospitals of reviewing a group of fees in aggregate rather than needing to regularly reassess the individual price points for all of the constituent costs.

Consistency

Most, if not all, of the items in this review can be considered disposable and/or consumable, and so it would be more consistent for these items to be treated similar to other disposable and consumable items.

In addition, this approach would be consistent with the approach of other private funders such as Workers Compensation schemes, Compulsory Third Party insurers and the Department of Veteran Affairs where consumable and disposable items are typically included within case based payments or bundled theatre fees, with additional fees for high cost items only in exceptional circumstances.[11]

[11] https://www.sira.nsw.gov.au/__data/assets/pdf_file/0019/613009/Private-Hospital-Maximum-Rates-Order-2020.pdf

Feasibility

For the lower cost items where a range of alternative products might be able to perform similar clinical roles, the change in funding mechanism should not impact the volume and range of items stocked by hospitals and should therefore have limited impact on clinicians' choices – apart from potentially to improve cost effectiveness as discussed under 'efficiency' above.

Several items that have shown sudden increased usage since listing (see Section 4.4.2), have previously been funded through case based or bundled payments.

This demonstrates that funding these items in this way is a feasible option.

Recommendation 2: tighten listing criteria

Amend the listing criteria in the Prostheses List Guidelines to include an overall intention for the PL and to remove any ambiguities.

As well as being the means to achieve Recommendation 1, this will limit the potential for future 'creep' in the nature of the items included on the PL. By including an overall intention for the PL, it will be more apparent when items on the PL are inconsistent with this intention. This should describe how the PL is intended to enable patients to have access to safe, clinically effective and cost effective prosthetic items through guaranteeing appropriate funding levels towards those prosthetic items that are critical and specific to meeting certain patients' needs – with these latter circumstances expanded on depending on the Department's views. For example, it might elaborate to say that it is intended to support patients where the implantation of a long-term prosthetic item would be the most important surgical option available that would improve their health outcomes.

In addition, adding additional details and definitions to clarify the specific ambiguity issues identified described in Finding 4.3.2 (2) will enable a more objective assessment of an item's eligibility (or otherwise) for inclusion.

Recommendation 3: improve listing processes

Improve robustness of listing processes, including: assessments for inclusion; assessments for reclassification; monitoring of appropriateness of usage; and regular assessments of clinical value.

Ideally the assessment processes for inclusion and reclassification on the list would include a comprehensive assessment that considers:

- Whether it meets the (more objective) listing criteria;
- Transparent tendering processes – i.e. opening up the process so that other manufacturers can simultaneously propose benefit amounts for their own similar products;
- The clinical value of the product relative to its proposed benefit amount and the benefit amounts of similar products (including other products included in the tendering process as noted above, and also other products that are on the PL and not on the PL); and
- Whether more efficient funding mechanisms might exist.

Ideally these assessments would be performed by an independent panel comprising members with a range of clinical and health economics backgrounds.

In addition, regular and formal monitoring of usage and compliance with the criteria should be performed and reported to the panel. The panel should also have a framework in place for reviewing and assessing the clinical value of items on the PL.

6.2.2 Transition considerations

As noted above, there is no suggestion that any of these items do not serve a clinical purpose in providing for optimal patient outcomes. As such, it would be an adverse outcome if removal from the PL led to an increased cost burden for clinically essential items and/or a reduction in usage to the extent that clinical outcomes for patients were compromised.

A range of implementation issues should be considered in order to avoid unintended consequences from the removal of any items.

Most importantly, the processes and contractual mechanisms for including these items within case based or bundled payments will need to be developed and tested so that there are no short-term adverse impacts on clinical outcomes and the cost of services. In particular, hospitals and clinicians will need to properly develop, test and implement procurement and usage monitoring processes and, given the clinical importance and volume of usage of these items, appropriate transition time should be allowed for this.

Most of the relevant items are relatively low cost. For example, the top 10 items used in FY19 had a weighted average prostheses list benefit of $166. Additionally, of these top 10 items, 5 had a benefit below $50, with these 5 items accounting for 43% of the top 10 item usage in FY19. For the lower cost items, their inclusion in the case based or bundled fee would represent a marginal increase in the total cost that might be difficult to distinguish from other cost fluctuations for other items already covered by case based payments or the theatre fee.

However, there are some higher cost items. For example, from the top 10 PL benefit growth items between FY14 and FY19, one had a benefit amount of more than $1,000 in FY19. More detailed analysis of the impact of including these items within the case based or bundled fee should be performed to determine if, and the extent to which, their inclusion should lead to a direct explicit change in the relevant fee.

Other transitional arrangements to consider include for existing contractual arrangements and other agreements to expire and for new arrangements to be agreed.

7. Reliances and limitations

This report was prepared at the request of the Department solely for the purposes set out in the scope section/proposal (hereafter "the Project") pursuant to the terms of our engagement letter dated 7 January 2020 and it is not appropriate for use for other purposes.

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In carrying out the work and preparing this report, EY has worked solely on the instructions of the Department, and has not taken into account the interests of any party other than the Department. The report has been constructed based on information current as of 8 May 2020, some of which has been provided by the Department. Since this date, material events may have occurred since completion which is not reflected in the report. The report is based in part on information and data supplied by the Department. We have not sought to verify the accuracy of data or information provided to us by the Department.

Other specific limitations to the report are described in Section 3.3.

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Appendix A Prioritisation of groups

As discussed in Section 4.1, the analysis into the various groups comprising the GM category of the PL was performed in line with an initial prioritisation lens provided by the Department and overlaid with a further risk-based prioritisation based on high-level analysis of usage and benefits data at a group level. Out of the 43 product groups from the GM part of the PL as at February 2020, 19 were classed as 'High' priority by the Department, and 12 of these were selected for more detailed analysis in this document.

Table 16 provides a summary of the outcomes of this prioritisation. Each of the 43 product groups from the GM part of the PL are shown with the initial prioritisation provided by the Department indicated. The total amount of PL benefits paid with respect to each group for FY19 is also included. For each of the 'High' priority groups identified by the Department, there are additional indicators for whether this group was deemed to constitute a 'High usage' group and a 'High growth' group (in respect of total benefits paid). Groups that were determined as being of priority focus for this document have been highlighted in grey.

Table 16 – Summary of prioritisation of GM product groupings

Product Group	DoH priority	Total Benefits FY19 ($)	High usage^	High growth^
03.01.01 - Hepatic, Yttrium 90, Standard Dose	Low	1,664,324	N/A	N/A
03.01.02 - Prostatic I-125	Low	1,888,523	N/A	N/A
03.01.03 - Tissue Expander/Separator	Low	2,734,526	N/A	N/A
03.02.01 - Infusion Ports	High	270,453	✗	✓
03.02.02 - Infusion Pumps, Balloon Based	High	5,802,268	✓	✓
03.02.03 - Infusion Pumps, Battery Powered (Part A)#	High	4,386,597	✓	✓
03.02.03 - Infusion Pumps, Battery Powered (Part C)#	Low	3,202,309	N/A	N/A
03.02.04 - Infusion Pumps, Spring Powered	High	748,670	✗	✗
03.02.05 - Infusion Pump Accessories (Part A)#	High	959,657	~	✓
03.02.05 - Infusion Pump Accessories (Part C)#	Low	0	N/A	N/A
03.02.06 - Pharmaceutical Beads	High	108,853	✗	✗
03.03.01 - Feeding Tubes	Low	2,366	N/A	N/A
03.03.02 - Gastrostomy Tubes	Low	139,110	N/A	N/A
03.03.03 - Jejunostomy Tubes	Low	79,492	N/A	N/A
03.03.04 - Caecostomy Tubes	Low	19,566	N/A	N/A
03.04.01 - Adjustable Gastric Band with Port	Low	1,738,374	N/A	N/A
03.04.02 - Gastric Band without Port	Low	2,318,549	N/A	N/A
03.04.03 - Replacement Injection Ports	Low	79,016	N/A	N/A
03.05.01 - Occluder Pin	High	1,633	✗	✗

Product Group	DoH priority	Total Benefits FY19 ($)	High usage^	High growth^
03.05.02 - Powder	High	723,648	✗	✓
03.05.03 – Sponges*	High	617,106	✗	✗
03.05.04 - Pliable Patches	High	3,014,999	✓	~
03.05.05 - Matrix	High	30,306,870	✓	✓
03.05.06 - Foam	High	2,124,130	✓	✓
03.06.01 - Biliary Stents	Low	2,872,362	N/A	N/A
03.06.02 - Colonic Stents	Low	20,411	N/A	N/A
03.06.03 - Oesophageal Stents	Low	805,385	N/A	N/A
03.06.04 - Pancreatic Stents	Low	246,904	N/A	N/A
03.06.05 - Enteral Stents	Low	735,665	N/A	N/A
03.06.06 - Tracheobronchial Stents	Low	113,050	N/A	N/A
03.06.07 - Nerve Repair Stents	Low	151,125	N/A	N/A
03.07.01 - Drainage Catheters	Low	615,878	N/A	N/A
03.07.02 - Endobronchial Valve	Low	1,300,194	N/A	N/A
03.07.03 - Drainage Shunts, Peritineovenous	Low	6,270	N/A	N/A
03.08.01 - Adhesion Barriers	High	4,576,998	✓	~
03.08.02 - Internal Adhesives	High	42,980,168	✓	✓
03.08.03 - Ligating Devices	High	27,309,106	✓	~
03.08.04 - Staples & Tackers	High	95,918,339	✓	✓
03.08.05 - Polypropylene/Polyester Mesh	High	3,652,428	✓	✗ Significant decreases
03.08.06 - Composite Mesh	Low	7,181,089	N/A	N/A
03.08.07 - Complete Biomaterial Mesh	Low	2,873,976	N/A	N/A
03.08.08 - PTFE/ePTFE Mesh	Low	106,794	N/A	N/A
03.08.09 - Plugs	Low	1,126,219	N/A	N/A
03.08.10 - Anastomosis Clip	High	34,661	✗	✗
03.08.11 - Dynamic Wound Closure Devices	High	6,720	✗	✗

*Represents a high utilisation group with very low average benefit per item
^Only considered for groups specified as 'High' priority by the Department
#Indicates groups which include products on both Part A and Part C of the PL

Appendix B Usage by subgroup for 'High' priority groups

This appendix gives usage data (from the HCP1 dataset) for some of the subgroups within several 'EY High priority' groups identified.

At the subgroup level, usage information is potentially commercially sensitive due to the small number of sponsors involved and so only limited additional information (to what is in the main body of the report) has been included in this Appendix. Where possible, for each group, the data shown is:

- The range of benefit amounts on the PL and the total benefits paid in FY19, by subgroup;
- Trends in item usage, total benefits paid, growth in total benefits paid and the average benefit amounts per item used, by subgroup; and
- Usage with other categories on the PL in dollar terms and proportional terms.

03.02.02 – Infusion Pumps, Balloon Based

Table 17 – Balloon Based Infusion Pumps subgroups

Product Sub-Group	Benefit amount on the PL ($)	Total Benefits Paid in FY19 ($)*
03.02.02.01 - Fixed Flow Rate	50 - 260	4,003,213
03.02.02.02 - Variable Flow Rate	142 - 450	1,799,055
Total	-	**5,802,268**

Figure 39 – Infusion Pumps, Balloon Based– Item usage by subgroup

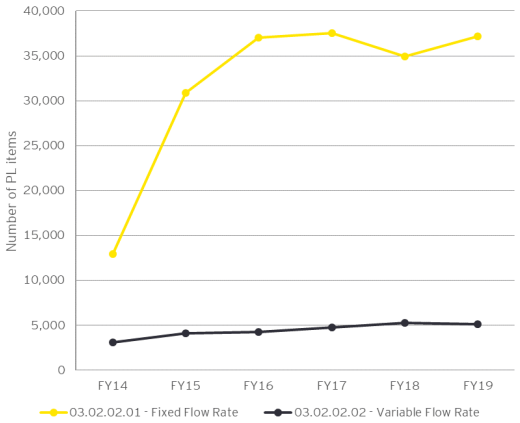


Figure 40 – Infusion Pumps, Balloon Based – Total PL benefits by subgroup

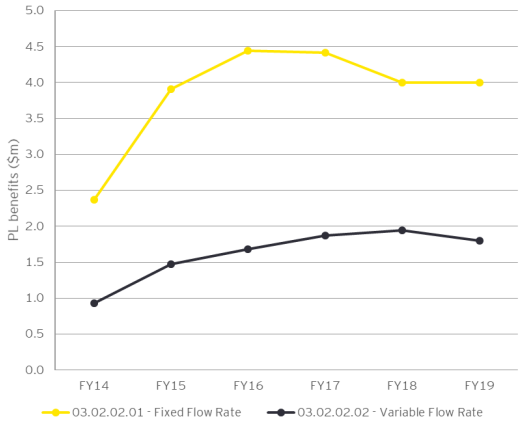


Figure 41 – Infusion Pumps, Balloon Based – Year on year growth in benefits by subgroup;

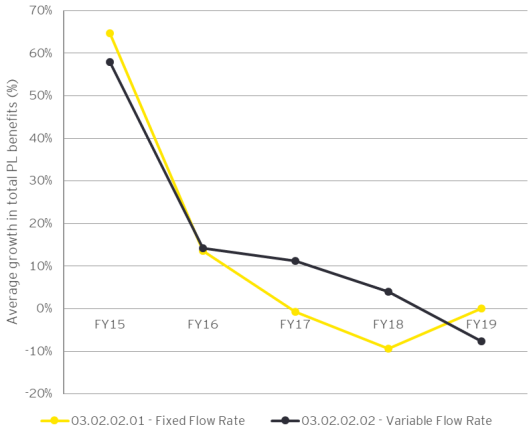


Figure 42 – Infusion Pumps, Balloon Based – Average benefit per item by subgroup

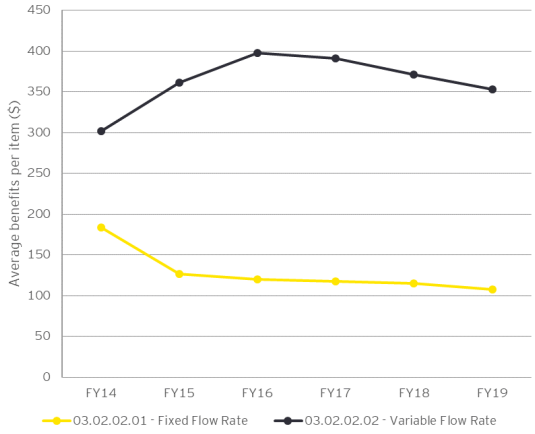
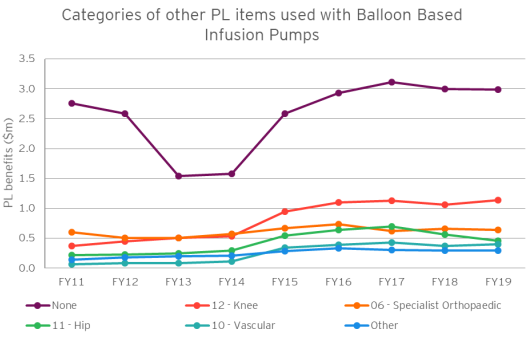
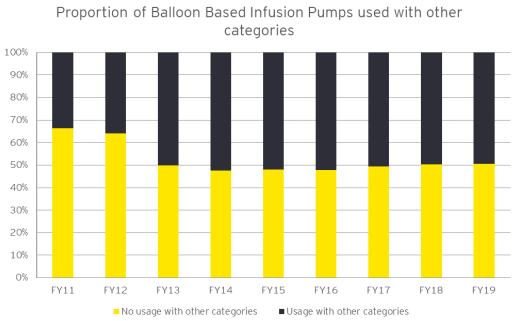


Figure 43 – Infusion Pumps, Balloon Based – Usage with other PL categories

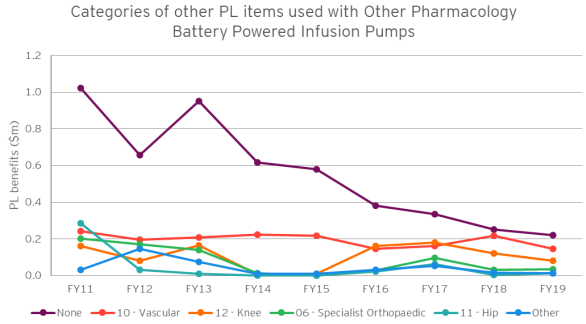


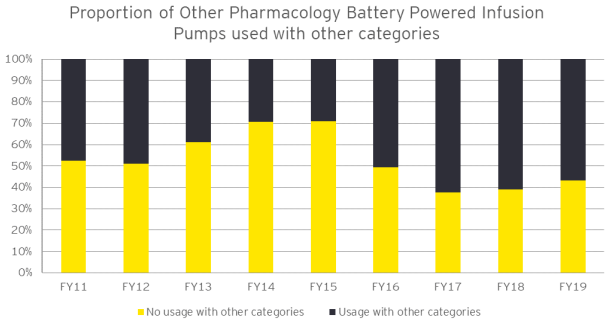


Note: usage with other categories excludes usage with other high priority GM items

03.02.03 – Infusion Pumps, Battery Powered

Figure 44 – Battery Powered Infusion Pumps – Other Pharmacology – Usage with other PL categories

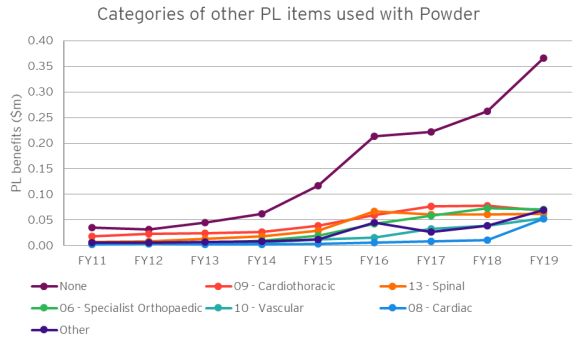


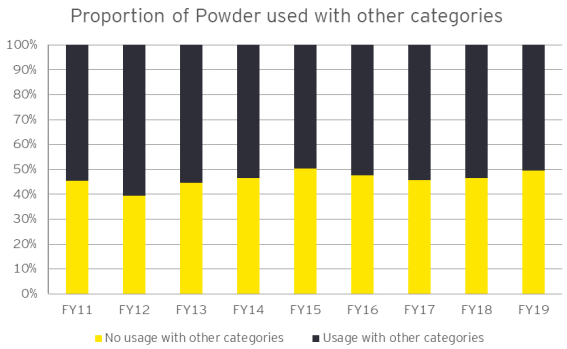


Note: usage with other categories excludes usage with other high priority GM items

03.05.02 – Powder

Figure 45 – Powder – Usage with other PL categories

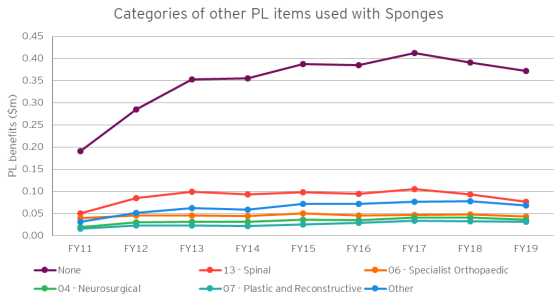


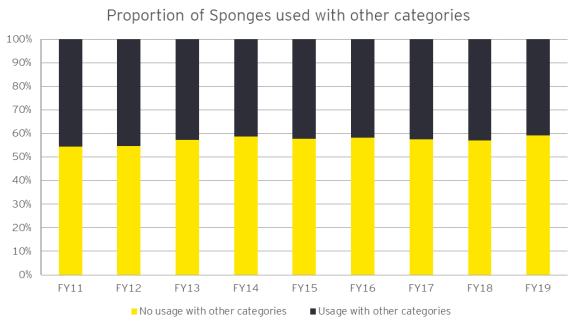


Note: usage with other categories excludes usage with other high priority GM items

03.05.03 – Sponges

Figure 46 – Sponges – Usage with other PL categories

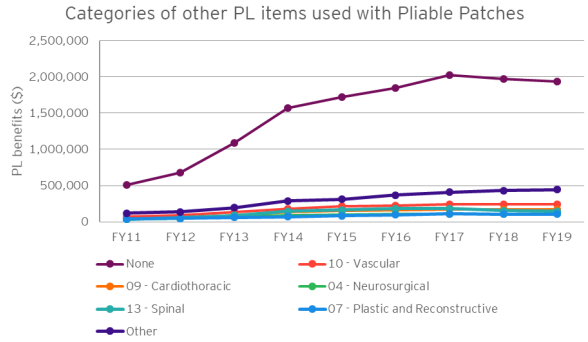


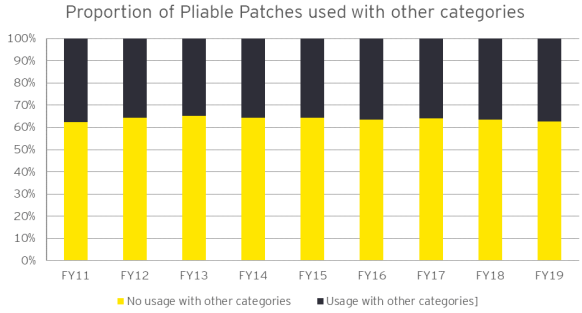


Note: usage with other categories excludes usage with other high priority GM items

03.05.04 – Pliable Patches

Figure 47 – Pliable Patches – Usage with other PL categories

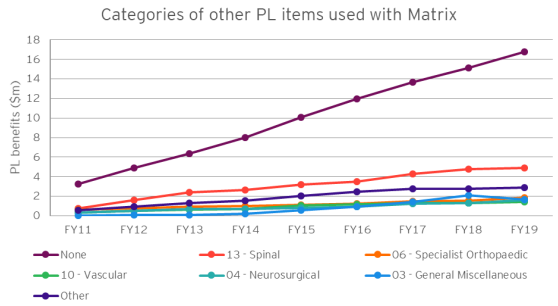


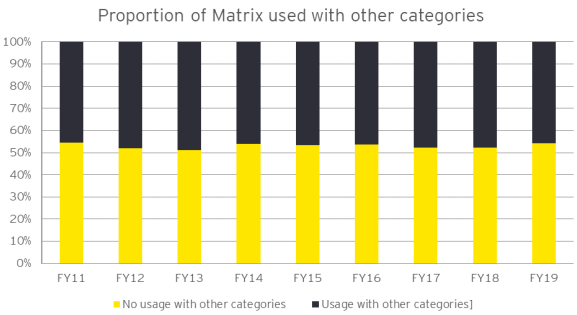


Note: usage with other categories excludes usage with other high priority GM items

03.05.05 – Matrix

Figure 48 – Matrix – Usage with other PL categories





Note: usage with other categories excludes usage with other high priority GM items

03.05.06 – Foam

Table 18 – Foam subgroups

Product Sub-Group	Benefit amount on the PL ($)	Total Benefits Paid in FY19 ($)*
N/A – no sub-groups	136 - 150	2,124,130

*per the Department's HCP dataset, which is 95% complete compared to APRA data

Figure 49 – Foam – Item usage by subgroup

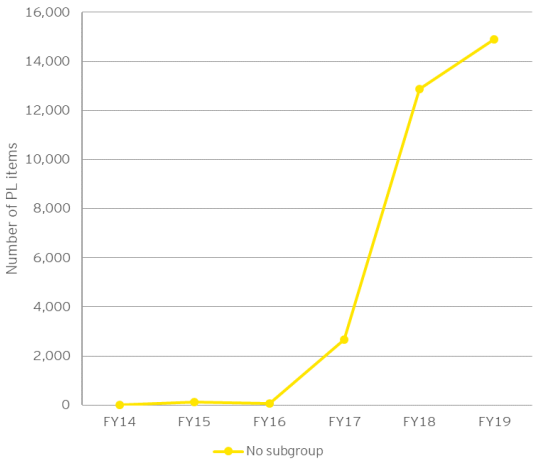


Figure 50 – Foam – Total PL benefits by subgroup

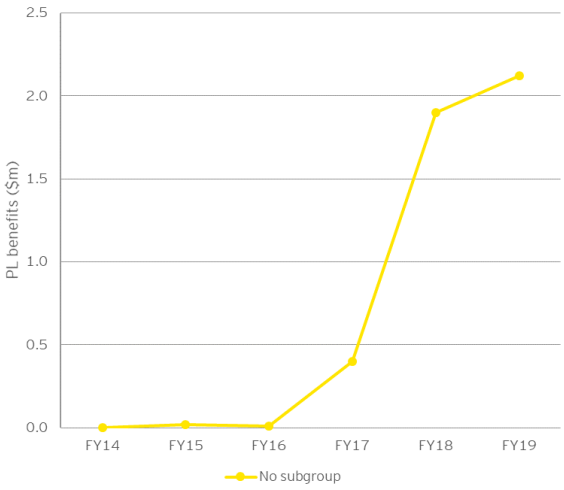


Figure 51 – Foam – Year on year growth in benefits by subgroup

Figure 52 – Foam – Average benefit per item by subgroup

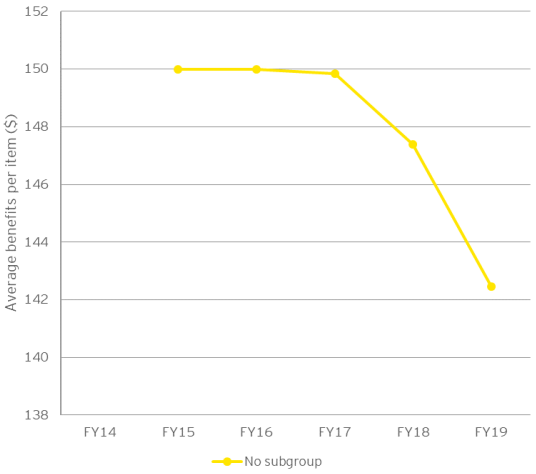
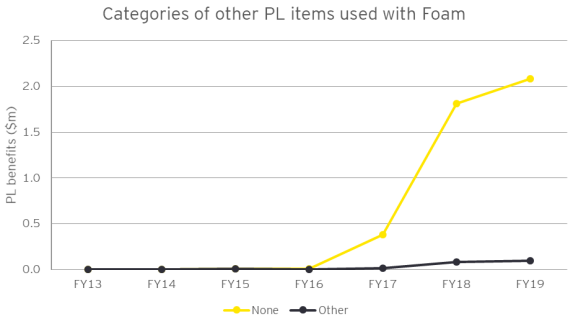
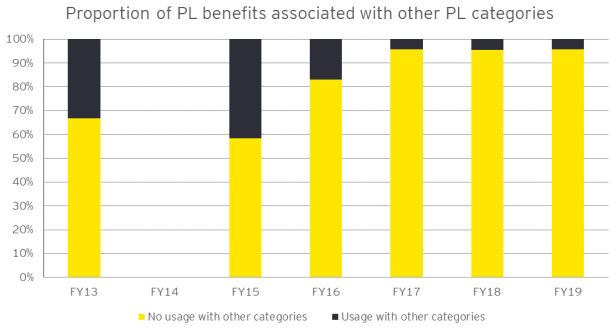


Figure 53 – Foam – Usage with other PL categories

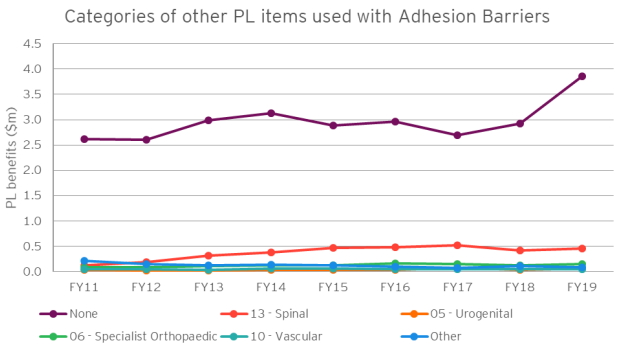


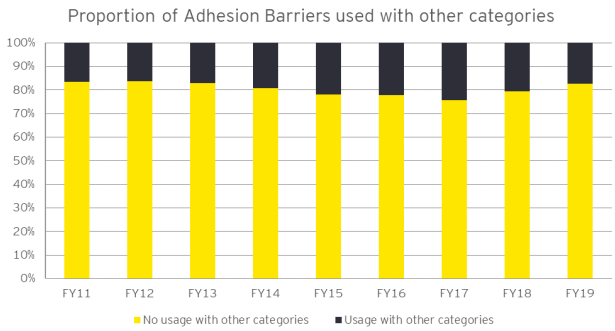


Note: usage with other categories excludes usage with other high priority GM items

03.08.01 – Adhesion Barriers

Figure 54 – Adhesion Barriers – usage with other PL categories

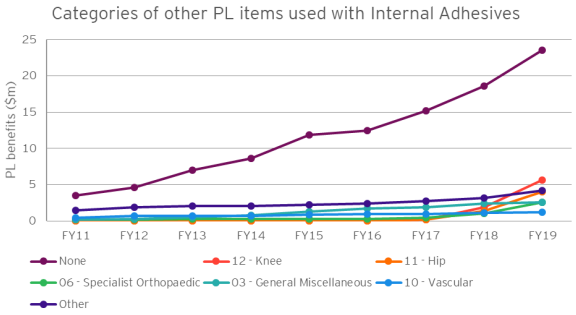


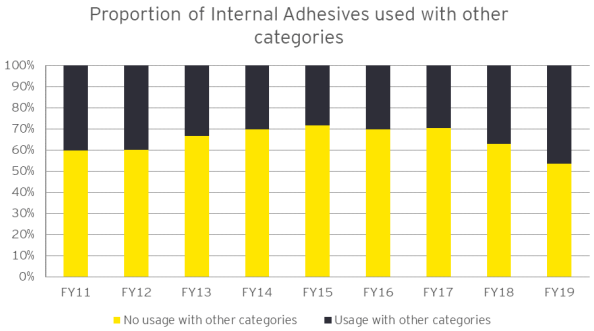


Note: usage with other categories excludes usage with other high priority GM items

03.08.02 – Internal Adhesives

Figure 55 – Internal adhesives – usage with other PL categories

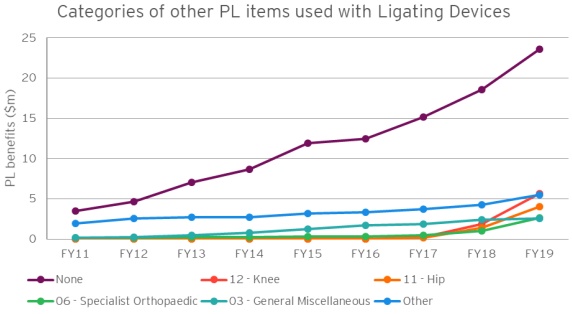


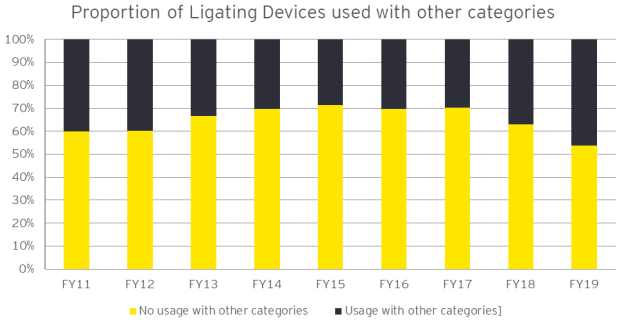


Note: usage with other categories excludes usage with other high priority GM items

03.08.03 – Ligating Devices

Figure 56 – Ligating devices – Usage with other PL categories

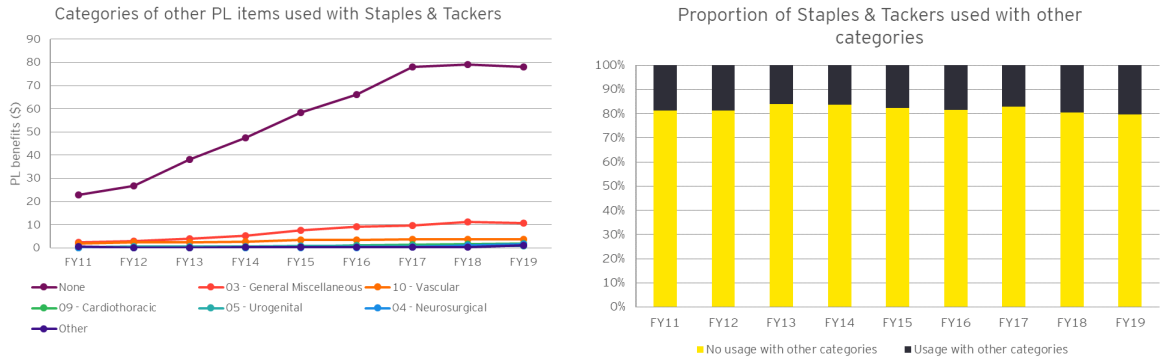




Note: usage with other categories excludes usage with other high priority GM items

03.08.04 – Staples and Tackers

Figure 57 – Staples and tackers – Usage with other PL categories



Note: usage with other categories excludes usage with other high priority GM items

Appendix C Detailed benchmarking analysis

Overview

This Appendix expands on the analysis in Section 4.5.4 where the benefit amounts on the PL were compared to the prices paid for the same items by public hospitals in two Australian jurisdictions.

As noted, there were many instances observed from the public hospital benchmarking data where the price paid by a public hospital mirrored the PL price. Since several products in this group are purchased in low quantities in the public realm, public hospitals often set the PL price as a ceiling price that they are willing to pay to suppliers for a one-time, non-committal purchase.

However, there were some product groups identified where significant pricing differentials were evident, and the PL benefit amount was higher than contracted prices in the benchmarked public health systems. In particular, the groups '03.05.05 – Matrix' and '03.06.03 – Oesophageal Stents' were cheaper by the largest amount. These groups are indicated by a '*' in the table below.

Further, for some of the high usage and fast-moving products, public hospitals were observed to be achieving prices up to 50% lower than the PL price through market share or volume commitments with suppliers. Many public hospitals across Australia use a competitive tendering process to drive down the price of prostheses, medical equipment and consumables in order to reduce their operating costs. In some cases, these procurement mechanisms also offer market share or volume commitments to suppliers in exchange for further reduced pricing.

Currently, the PL mechanism does not allow private hospitals to achieve access to such pricing. Given the high usage in the private healthcare system, as well as the strong competition between suppliers in the market, these price savings could potentially be leveraged by private hospitals if some of these products were to be removed from the PL and contracted through competitive tendering processes by private hospital owners.

While this benchmarking exercise sheds light on some product groups that have been more subjected to price inflation on the PL than others, a more in-depth analysis of current operational practice both in the public and private sector could identify further explanation for price differentials, and potential identify gaps in current practice.

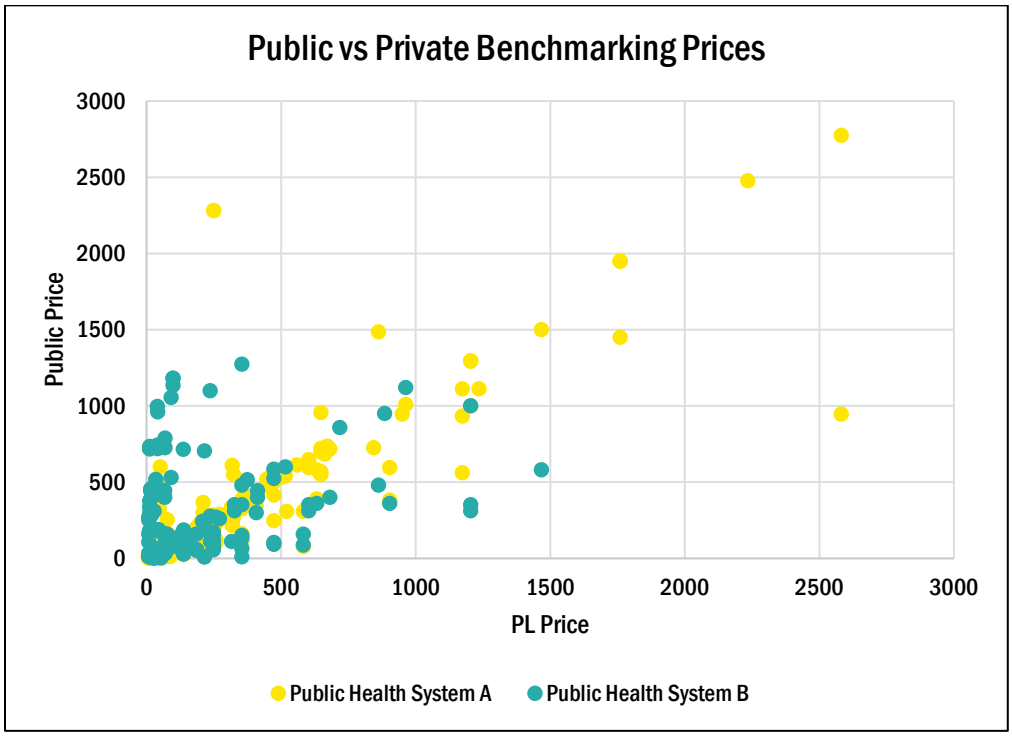
The table and figure below summarise the findings of the price benchmarking exercise.

Table 19 – PL vs public prices by GM product group

Sub Category	Benchmarked Product Group	Best Prices Observed
03.01 – Brachytherapy	03.01.03 – Tissue Expander / Separator	Public
03.02 – Drug Delivery Devices	03.02.05 – Infusion Pump Accessories	Public
	03.02.06 – Pharmaceutical Beads	Private
03.03 – Enteral Tubes	03.03.02 – Gastrostomy Tubes	Private
03.04 – Gastric Bands	03.04.01 – Adjustable Gastric Band with Port	Public
03.05 – Haemostatic Devices	03.05.02 – Powder	Private
	03.05.03 – Sponges	Private
	03.05.04 – Pliable Patches	N/A

Sub Category	Benchmarked Product Group	Best Prices Observed
	03.05.05 – Matrix	Public*
03.06 – Luminal Stents	03.06.01 – Biliary Stents	Private
	03.06.02 – Colonic Stents	N/A
	03.06.03 – Oesophageal Stents	Public*
	03.06.04 – Pancreatic Stents	Private
	03.06.05 – Enteral Stents	Public
	03.06.06 – Tracheobronchial Stents	Public
	03.06.07 – Nerve Repair Stents	Private
03.07 – Pulmonary / Peritoneal Devices	03.07.01 – Drainage Catheters	Public
	03.07.02 – Endobronchial Valve	Private
03.08 – Closure Devices	03.08.01 – Adhesion Barriers	Public
	03.08.02 – Internal Adhesives	N/A
	03.08.03 – Ligating Devices	N/A
	03.08.04 – Staples & Tackers	Private
	03.08.05 – Polypropylene / Polyester Mesh	Private
	03.08.06 – Composite Mesh	Private
	03.08.07 – Complete Biomaterial Mesh	Private
	03.08.08 – PTFE / ePTFE Mesh	Private
	03.08.09 - Plugs	Private

Figure 58 - Benchmarking of GM PL item prices between public and private health systems



03.01 – Brachytherapy

Benchmarking data for this product category shows that PL pricing is uncompetitive when compared to public hospital benchmarks. For instance, one product was observed to be purchased in a major Australian public health system for 6% cheaper than the PL price.

03.02 – Drug Delivery Devices

Several products in the '03.02.06 - Pharmaceutical Beads' group were observed to be purchased in a major Australian public health system for prices 5% to 11% higher than the PL price. Only one product in this group was observed at an 18% lower price than the PL.

In addition, some instances of volume-discounted pricing were observed in the '03.02.05 - Infusion Pump Accessories' group. For instance, the one-off, non-committal prices offered to the public health system by a supplier was $1 or 4% cheaper than the PL. However, with an increased volume commitment from a hospital within this state, this supplier had offered to discount this product to 58% cheaper than the PL price.

03.03 – Enteral Tubes

Benchmarking data for this product category indicated that for most products, the Private PL offered more favourable pricing when compared to the prices observed in public sector. The benchmarked public prices ranged from 5% to 31% more expensive that the PL price. However, two items were purchased at 61% and 34% cheaper in the public hospital setting.

03.04 – Gastric Bands

Benchmarking data for this product category shows that PL pricing is uncompetitive when compared to public hospital benchmarks. For instance, the price of one Gastric Band product was observed to be contracted to a major Australian public health system at 13% cheaper than the PL price.

03.05 – Haemostatic Devices

Benchmarking data for '03.05.02 – Powder' indicated that for most products in this group, the PL offered more favourable pricing when compared to the prices observed in public sector. The benchmarked public prices ranged from 5% up to 62% more expensive that the PL price. However, an instance of volume-discounted pricing was observed for one Powder product. While the one-off unconditional price offered to a public health system was 5% more expensive than the PL price, for a significant market share commitment to the supplier in that product category, the price offered was reduced to 28% cheaper than the PL price.

Similarly, prices observed in the public sector for products in the '03.05.03 – Sponges' group were predominantly more expensive than prices on the PL. The benchmarked public prices ranged from 13% to 70% more expensive that the PL price.

A broad range of prices were observed in the public health benchmarking data for the group '03.05.04 - Pliable Patches' that were both higher and lower than the PL prices. The average price paid across the two benchmarked public health systems was 4% cheaper than the PL.

However, prices paid in the benchmarked public systems for '03.05.05 – Matrix' products were significantly cheaper than prices listed on the PL, with benchmarked pricing being 8% to 60% more favourable in the public system.

03.06 – Luminal Stents

Across the group for '03.06.01 - Biliary Stents', most items in the '03.06.01.01 – Non-reinforced Wall' subgroup were observed to be sold in the benchmarked public health systems for 5% to 11% higher than the PL price, while items in the subgroups '03.06.01.02 -Reinforced-wall, Uncovered/Bare Metal' and '03.06.01.03 – Reinforced Wall, Covered' were in some instances up to 34% more expensive than the PL price. There were only some instances where volume-discounted pricing allowed the public hospital to achieve prices that were 8% to 10% cheaper than the PL pricing in return for commitment of an extremely large market share in that hospital's total purchasing of Biliary Stents.

Benchmarked prices for the group '03.06.03 - Oesophageal Stents' were between 2% to 34% cheaper in the public health systems compared to the PL. For instance, different products were seen in the public system at prices 22%, 23%, 34% and 21% cheaper than their respective PL prices.

The pricing of almost all products in the '03.06.04 - Pancreatic Stent' group appeared to be more favourable on the PL when compared to the benchmarked public health systems. Only one product had a price observed that was lower in the public system, provided at a price 24% cheaper than the PL price. Similarly, Nerve Repair stents were observed to have more favourable pricing on the PL than in the public sector.

However, a contrary differential was observed in the '03.06.05 - Enteral Stent' and '03.06.06 - Tracheobronchial Stent' groups. Products in these groups contracted to the benchmarked public health systems were between 5% and 34% cheaper that the PL pricing. Further, prices paid for '03.06.02 - Colonic Stents' in the benchmarked public health systems appeared to mirror the PL pricing, which could likely be attributed to the low purchasing volumes in this product group.

03.07 – Pulmonary/Peritoneal Devices

Across the group for '03.07.01 - Drainage Catheters', pricing observed from the public benchmarking data was predominantly cheaper than that observed on the PL. For instance, one product on the PL

was under contract with an Australian public health system for 16% cheaper than the PL price. In addition, another was also being bought by the same public health system at a price 12% cheaper than the PL price. Similar price differentials were seen across this product group.

However, prices benchmarked for '03.07.02 - Endobronchial Valves' were 5% more expensive in the public contract prices, compared with the PL price. One product was purchased in the benchmarked public health system at a price which is 5% more expensive than the PL price.

03.08 – Closure Devices

Benchmarking data on '03.08.01 - Adhesion Barriers' indicated that pricing offered by medical device manufacturers to the public system was more favourable than prices existing on the PL. For instance, one Adhesion Barrier product was contracted to a public health system for less than half the PL price, indicating that pricing for this particular product was 52% more favourable in the public realm. Further, some suppliers offered market share discounts in this product category, bringing the price differential between public and private prices even further apart. The one-off unconditional price for another product in this group provided to one public health system was 20% cheaper than the PL price. However, if a hospital within that public health system elected to provide the supplier with a significant volume of market share within that product category, they reduced the price to 30% cheaper than the PL price.

Benchmarked prices for products in the '03.08.02 - Internal Adhesives' and '03.08.03 - Ligating Devices' product groups showed a variety of pricing that was both higher and lower than the PL. However, some concerning pricing differentials were flagged for some high-usage products that was significantly lower in the public system. For instance, one particular product is 17% lower in both benchmarked public health systems compared to the PL. Similarly, another was contracted to one public health system for 13% lower than the PL price. With respect to '03.08.03 - Ligating Devices', one product in this group was observed to be under contract with both benchmarked public health systems for a price which is 12% cheaper than the PL.

The average price of a product within the '03.08.04 - Staples & Tackers' group is 23% higher in an Australian public health system than the PL. A large portion of the benchmarked products in this group were observed to be priced 1% to 9% higher than the PL.

Similarly, pricing appeared to be more favourable on the PL than the benchmarked prices observed in the public health systems for all of the groups of Mesh, including '03.08.05 - Polypropylene/Polyester Mesh', '03.08.06 - Composite Mesh', '03.08.07 - Complete Biomaterial Mesh', '03.08.08 - PTFE / ePTFE Mesh' and '03.08.09 – Plugs'. However, public pricing observed in the '03.08.09 – Plugs' product group showed that there were some instances in which public hospitals were accessing prices that were lower than the PL for products in this category. For example, one Plug product was contracted to a public health system for 26% cheaper than the PL price.

Appendix D Stakeholder feedback

Consultation process

As described in Section 3.2.3, engagement with stakeholders was conducted by the Department via a PHI Circular to registered parties, and via letter and email to organisation who provided feedback on the Terms of Reference. All stakeholders, including providers, manufacturers, insurers and other interested parties were requested to make submissions via the Consultation Hub.

The remainder of this appendix is a summary of the key details highlighted through stakeholders across the submissions received during the stakeholder consultation period. Whilst not exhaustive, this feedback provides context for, and insight into, the usage, pricing, categorisation and listing criteria for several GM categories on the PL, as well as potential unintended consequences of removal of products from the PL.

Listing criteria and process

03.01 – Brachytherapy

There was general opinion across the three stakeholder groups that Brachytherapy could be considered as a delivery mechanism of treatment as opposed to a true prosthesis implant. While the seeds are a justified treatment modality, the devices do not play a role in replacing a bodily function or modulating an ongoing physiological process. The procedure could instead be covered under diagnostic reference group (DRG) payment mechanisms, with the seeds included as part of the procedure.

03.02 – Drug Delivery Devices

There was feedback across all stakeholder groups that while drug delivery devices play a critical role in the overall treatment of patients, they may be more appropriately covered within the hospital DRGs as they are a standard tool used for the delivery of medication, and they are not a true leave-behind device that remains in the body well after the patient has been discharged from the hospital. Further, many of the items in this category can be used for multiple times on different patients.

03.02.01 – Infusion Ports

One private health insurer communicated that while infusion ports are implanted, they do not remain in the body permanently.

03.02.02 – Infusion Pumps, Balloon Based

One private health insurer mentioned in their feedback submission that many of the infusion pumps can be used subcutaneously. In this case, their use would be considered as an outpatient service, and patients receiving slow release infusions over several days are also often discharged home while the infusion is completed. As a non-permanent device used to deliver medications on a short-term basis, they do not meet the specifications of the PL.

In addition, another articulated that the disposables that are paid for as part of a ‘Set’ are expensive and are often included in the procedure costs in the delivery of medication.

03.02.03 – Infusion Pumps, Battery Powered

A private health insurer and a private hospital group both highlighted in their feedback that the listing of one manufacturer’s infusion pump notes that the product includes “an intuitive, full colour

touch screen interface", which is not implanted into the patient, and therefore not a prosthesis device. Several of the Private Health Insurers provided feedback that such capital equipment listed in this product group are not considered to be true prostheses, as they can be used in hospitals on multiple patients.

Another private health insurer communicated that as a result, items within this group are being purchased through the PL and returned to the hospital's capital equipment stock that can be used on the ward for inpatients as a means of reducing their capital expenditure. They noted that in this way, hospitals have no incentive to be cost-conscious about their choice of device. Further, the inclusion of these products on the List is advantageous to patients who do not initially use the equipment and damaging to the insurer who paid for the first user of the device.

Another claimed that these multiple-use items fail to satisfy the PHI Act requirement that they are 'provided' to a member, as the hospital retains full possession and ownership of the product for subsequent use on other patients, regardless of their insurance provider. This private health insurer was also concerned that this category of equipment may set a precedent leading to private health insurers being required to pay for other types of hospital capital equipment.

03.02.04 – Infusion Pumps, Spring Powered

One private health insurer communicated during the consultation process that benefits are also paid by private health insurers for disposable drug delivery items in this category. They stated that under the PHI Act, the requirement for an insurer to pay benefits for prosthetic items on the PL only applies when it is 'provided in circumstances where a Medicare benefit is payable'. However, it is reported that hospitals often claim benefits for these products despite there being no Medicare-rebatable service directly associated with the provision of prosthetic items. Further, they claimed that the nature of these practices has led to some private hospitals claiming prostheses benefits for disposables which are disproportionate to the size of their facilities, meaning that smaller hospitals were claiming comparably greater volumes of disposables than larger hospitals.

03.02.05 – Infusion Pumps Accessories

Some private health insurers referred to the fact that Infusion pump accessories are mostly disposable, single-use items, and not prostheses that remain in the body permanently. For example, Administration Sets must be changed every 24 or 72 hours, depending on the condition and medication.

One manufacturer identified that alternative funding mechanisms do exist for five products within the Administration Reservoir and Administration Set sub-groups, as they are listed on the National Diabetes Services Scheme (NDSS) insulin pump consumables order form and can be accessed through the NDSS.

Further, a private health insurer said that certain Administration Sets are available in the market for consumers to purchase in sets of 50 for $214.85 (or $4.29 each) without any requirement for verification of status. These products appear on the PL for $7 each, and the insurer has recorded usage increasing by 200% in 12 months.

03.02.06 – Pharmaceutical Beads

One private health insurer suggested that given that pharmaceutical beads are an alternative method of medication administration to syringes and needles, they could be covered through a similar hospital treatment funding mechanism.

03.03 – Enteral Tubes

A private health insurer and a private hospital group both communicated that while Enteral Tubes are implantable devices, many of these items are not permanent, and are only used temporarily while the patient receives critical care. The private health insurer mentioned that in some instances, the tubes may be used for longer periods of time, but they are replaced every 12 months, in an outpatient service. They also noted that the United Nations lists many of the products in this category as consumables, raising a question about the appropriateness of the listing of Enteral Tubes as a prosthetic product.

03.04 – Gastric Bands

A private health insurer and a private hospital group both agreed that all items in this category are permanent prostheses and meet the criteria for inclusion on the PL. However, the private hospital group suggested that given the price and competition in the market for gastric bands, private hospitals could consider case based, bundled or contracted arrangements rather than relying on the PL funding.

03.05 – Haemostatic Devices

Whilst it is recognised that haemostatic devices are clinically effective and cost effective in blood management. There was feedback from manufacturers, private health insurers and private hospitals alike that these items are not permanent in the body and do not act in an ongoing way to address a medical condition. One manufacturer noted that a temporary haemostat may only last several minutes in the body, and therefore, this product category may not be consistent to the intent of the PL when it was expanded to include new technologies that combat pathological and physical processes.

There was feedback across all three stakeholder groups that, in this way, such items could be considered as consumables, and reasonably be bundled into the cost of the procedure covered under DRG arrangements. One private health insurer commented that many insurers already have arrangements in place with providers as to how consumables are funded, so their additional payment through the PL mechanism could be considered a double payment for the same item used within a single procedure.

However, a manufacturer stated that the amount of these products required for a surgery is usually not predictable, or not known until the surgery has commenced, so there is a risk that these products may cost health insurers more if they are incorporated into a bundled payment, but are not used in a surgery. They commented that there may also be further implications on blood products funded by National Blood Authority (NBA) if the items were to be removed from the PL, as the use of these products may increase and impact patient outcomes.

Another private health insurer mentioned in their feedback submission that the listed price of some items is inflated when compared to the cost of attaining a similar item from other medical supply sources. For instance, when a patient receives in-chair dental surgery, they are not charged any additional fees for sponges that are used throughout the procedure as they are inherent to the procedure itself.

03.05.03 – Sponges

Some private health insurers commented that Sponges were used in surgery for a long time prior to listing on the PL, which has resulted in private health insurers paying twice for these products. Further, it was identified by a private health insurer that a sponge product listed on the PL is available as a code in Eclipse, meaning that hospitals can claim funding for this product from private

health insurers through in-hospital claiming arrangements. However, many hospitals continue to purchase it from the PL at a higher non-negotiated price.

03.05.04 – Pliable Patches

One private health insurer commented that the usage instructions of a certain Pliable Patch on the PL state that the sponge must always be removed after haemostasis is achieved as it could swell and exert unwanted pressure in the affected area. Therefore, they conclude that this product is not implanted and serves no permanent role in the body, thus precluding the product from the definition of a prostheses.

03.05.05 – Matrix

One private health insurer communicated that similar items or substitute items as those listed in this sub-category, are also funded by private health insurers through case based payments or theatre banding.

03.05.06 – Foam

A private health insurer and a private hospital group both commented that one foam product on the PL is already funded through DRG and case payments. They both stated that these products can also be used outside of the operating room, such as on football fields to treat sports injuries.

03.06 – Luminal Stents

A private health insurer and a private hospital group both stated that Luminal Stents clearly meet the criteria for inclusion on the PL, as they permanently remain in the patient's body. However, they also communicated that all items in this category could be captured through case based, bundled or contracted arrangements with suppliers given their price and competition in the market.

03.07 – Pulmonary / Peritoneal Devices

03.07.01 – Drainage Catheters

One private health insurer commented that Drainage Catheters are used temporarily while a procedure is being performed, and do not permanently remain in the body. Further, one manufacturer noted that while they are inherent in the surgery, it could be envisioned that such low-cost products could be removed from the List without too much trouble if hospitals were given notice to plan for these additional costs, and if they could be bundled into existing DRG payments.

03.07.02 – Endobronchial Valves

A private health insurer and a private hospital group both communicated that Endobronchial Valves remain permanently in the body and have an ongoing function. They both suggested that these items could be captured either by assignment to an alternative category or through case based, bundled or contracted arrangements with suppliers given their price and competition in the market.

03.07.03 – Drainage Shunts, Peritineovenous

A private health insurer and a private hospital group both provided feedback that Peritineovenous Drainage Shunts also remain permanently in the body and have an ongoing function. Similarly, they suggested that these items could be captured either by assignment to an alternative category or through case based, bundled or contracted arrangements with suppliers given their price and competition in the market.

03.08 – Closure Devices

Feedback across all stakeholder groups recognised that this product category encompasses a varied nature of products, some being permanent and others being bioabsorbable. For those permanent items that remain in the body with an ongoing function, one private health insurer and one private hospital group suggested that they continue to form an inherent part of procedures and should therefore be considered for case based, bundled or contracted payment methods. A manufacturer also noted that despite their low cost per unit, products in these groups are permanent devices, and as such are distinct from the nature of items that are proposed for removal based on their temporary nature.

Several stakeholders commented that items that are not permanent and do not have an ongoing function, such as glues and other temporary consumable items in this category, do not meet the criteria for listing. A manufacturer stated that a temporary adhesive may only last several minutes in the body, and therefore, this product category may not be consistent to the intent of the PL when it was expanded to include new technologies that combat pathological and physical processes. There was feedback across all stakeholder groups that Adhesives are commonly used for general skin closure as a substitute for, or in addition to, sutures and could therefore be covered within the hospital admission DRG.

03.08.02 – Internal Adhesives

One private hospital group noted that there are two types of Internal Adhesives denoted by their respective suffix, Biologics and Synthetics, relating primarily to the source material. They commented that many of these products either substantially or wholly include pharmacological agents which exert a biochemical or physiological effect. With respect to the PL criteria, they state that these products do combat a pathological process or modulate a physiological process, however the presence of such pharmacological agents raises the question as to whether they may be more appropriately funded through the Pharmaceutical Benefits Scheme (PBS), rather than through the PL.

Within the Synthetic category, several private health insurers and medical device manufacturers noted that there are a range of products currently on the PL that are skin closure devices. They claimed that the description of these products highlight that they are topical skin adhesives, meaning they are not internally implanted but applied externally to the body. One manufacturer commented that these products are typically Class IIa devices as advised by the TGA, and they naturally fall off the skin after several days once the skin is healed. Since they are not implanted into the body, the manufacturer suggests these products may not fulfil the PL criteria as it was intended.

One manufacturer submitted feedback suggesting that these products could be considered inappropriate for listing, as they are a substitute for skin suture which are also covered under general hospital payment methods. They commented that in this instance, this product group displays traditional hallmarks of PL expansion where one listing has generated a flood of comparators based on the precedent of the first. The introduction and existence of one inappropriately listed item on the PL has given grounds for the addition of several comparator items.

In addition, feedback from some medical device manufacturers and private health insurers indicates that many of the items in this group were in use and funded through hospital-insurer agreements for several years prior to being added to the PL. They claim that, to this day, some skin glues and consumables such as sutures, skin staples, and dressings are bundled into funding arrangements within case based payments or theatre band charges, DRG or non-DRG case payments, and other funding structures. One private health insurer commented that historically, such funding

arrangements have not specified in itemised and named detail, consumables and disposables that are used in general surgical skin closure.

One private hospital group raised a concern that as listed devices are effectively funded in an uncapped manner by insurers, placing an item on the PL that is not implantable may distort the hospital's and clinician's assessment of cost-effectiveness. Private health insurers suggest that hospitals have an incentive to increase utilisation of devices, and in doing so, reduce expenditure on non-listed consumables. Therefore, insurers pay more, hospitals reduce their expenses, and device sponsors receive more revenue.

One manufacturer has identified that within two years of listing on the PL, private health insurers have been required to pay over $14m extra in payment for products used for skin closure, as an alternative to a skin suture. Many stakeholders have suggested that there is no evidence that the use of skin glues offer a benefit over a $10 - $15 foil, with no clear indication of superiority when it comes to complication rates.

03.08.03 – Ligating Devices

One private hospital group provided feedback that for high-volume, low-cost prostheses such as Ligating Devices, Staples and Tackers, the PL is a very inefficient funding mechanism. They suggested that bundled payments by procedures could be considered a more efficient way to fund these items. According to the group, such arrangements are already negotiated between private health insurers and hospitals, providing an incentive for hospitals to achieve the best possible price for suppliers. However, one manufacturer stated that there is often a large variation in the quantity of ligating devices required per procedure, and it is difficult to control their usage. Therefore, with such variation in usage, the manufacturer suggests that these products do not lend themselves easily to procedural based funding arrangements.

03.08.04 – Staples & Tackers

One private health insurer communicated that disposable and consumable components that may be used is loaded with staples is a consumable on the tray and covered as part of the procedure. They stated that these disposables and multi-purpose items are bundled, meaning they may be costed into a procedure and funded for by a private health insurer.

It was also identified by a private health insurer that a certain Non-bone (Reload) Staple is also available as a code in Eclipse, meaning that hospitals can claim funding for this product from private health insurers through in-hospital claiming arrangements. However, many hospitals continue to purchase it from the PL as it has a higher non-negotiated price.

03.08.05 – Polypropylene / Polyester Mesh

It was identified by one private health insurer that two products in this group are also available as codes in Eclipse, meaning that hospitals can claim funding for these products from private health insurers through in-hospital claiming arrangements. However, many hospitals continue to purchase them from the PL as a higher non-negotiated price.

Usage of GM Items

03.01 – Brachytherapy

One private health insurer reported a 35% increase in costs between 2018 and 2019 for Brachytherapy items. This included a 170% increase for one product and a 98% increase for another in the last 12 months.

03.02 – Drug Delivery Devices

One private health insurer reported exponential growth in this category, from $83,908 in 2017 to $491,068 in 2019, which is a growth of 485% over this two-year period. Another reported increases in use of 2,233%, 813%, 209% and 174% for four separate products in this group over 12 months.

03.02.03 – Infusion Pumps, Battery Powered

One private health insurer reported an instance of a private hospital claiming benefits for 23 Battery Powered Infusion Pump products between April 2016 and January 2017, for a total cost of $113,850. These included claims for two pumps for one patient on consecutive days of the same episode of care. They also reported that another private hospital claimed benefits for six Battery Powered Infusion Pump products between August 2016 and March 2018 at a total cost of $29,502.

03.04 – Gastric Bands

One private hospital group suggested in their feedback that the usage of Gastric Bands in both public and private hospitals has become almost obsolete since the normalisation of the gastric sleeve procedure. A private health insurer reported an overall reduction in prostheses costs for this category over the last 12 months, which is reflective of the move away from gastric banding towards gastric sleeve procedures for bariatric surgery.

03.05 – Haemostatic Devices

One private health insurer reported an 11% increase in prostheses costs for this category between 2018 and 2019. Of note, there was a 98% increase in prostheses costs for one particular product.

It was noted by stakeholders that other than cost and availability, there is no clinical reason for a clinician not to choose the larger version in all circumstances, even if the smaller size would suffice. It is difficult to know what volume is needed, so a clinician may choose to use the >6mL version due to the element of uncertainty.

03.07 – Pulmonary / Peritoneal Devices

One private health insurer reported a 498% increase in costs between 2018 and 2019 for products in this category, which they state is significantly greater than any record increase in hospital utilisation of relevant procedures.

03.08 – Closure Devices

One private health insurer stated that Closure Devices is the highest cost category for many private health insurers. They reported that between 2018 and 2019, the costs associated with prosthetic items within this category increased beyond what would be considered reasonable for hospital utilisation. For example, during this time period there was a 2,282% increase in one Non-bone (Reload) Staple product, a 456% increase in one Synthetic Adhesive product, and a 744% increase in one Reinforcer Staple product.

03.08.02 – Internal Adhesives

One private health insurer reported that there have been dramatic year-on-year increases in spend in this category, from $6,600 in 2017, to $3.2 million in 2018, which further increased to $4.4 million in 2019. For several Internal Adhesives, private health insurers have recorded high growth in utilisation in the period between TGA approval and listing on the PL, with reports of 129% increase in volume and 56% increase in benefits paid over the past year.

One private health insurer reported that one internal adhesive product had seen volume and benefit increases of 450% in 2019, compared with 2018. Meanwhile, another had seen volume and benefit increases of more than 500% over the same period. Further, they reported that volumes for larger-sized formulations of a product had risen by more than 125% in less than one year. In addition, some items within the Adhesive Accessory sub-group saw corresponding increases of 146% utilisation and 132% benefit cost increases according to the private health insurer.

Another communicated that it is difficult for private health insurers to ascertain how many closure devices, if any, were used in the closure, as it is not specified in the procedure itself. Further, they indicated in their response that all product sub-groups structured in size or volume tiers are exposed to gaming with waste. For instance, it seems that utilisation of larger-sized formulations have been encouraged, potentially resulting in significant waste. they allude to the fact that such waste cannot be identified or confirmed by auditing clinical records, and results in system inefficiencies.

03.08.03 – Ligating Devices

One private health insurer claimed that there may be some wastage in the usage of these products in a clinical setting. For instance, standard kits may be opened in multiple scenarios during a procedure as the disposable items are used. Additional items are available in the kit 'if required' and are disposed if not used in the procedure.

In addition, one manfuacturer notes that stakeholders have previously expressed concerns around reimbursement rates for Ligating Devices, and potential anti-competitive behaviour involved, based on a substantial yet largely 2 supplier market.

03.08.04 – Staples & Tackers

Some private health insurers provided feedback that recently there has been strong volume growth and benefit increases in the Staples & Tackers group. One reported volume growth in excess of 10% year on year. Stakeholders noted that advances in surgery have seen a move from open to keyhole surgery, leading to a more liberal usage of staplers, specifically articulating and roticulating staples. In addition, there has been a clinical preference for using reinforcer staples, as there is evidence referred to by Medical Device Manufacturers to suggest they provide benefits for leakage rates.

One private health insurer communicated that while it has since been removed from the PL, the previous listing of some products in this category have triggered impacts in the usage of other products in this category. Specifically, they suggest there may be a bias for more expensive staples and tackers to be used in procedures instead of cheaper alternatives such as standard sutures. They noted that one barbed suture item was removed from the list due to reasoning that it did not meet the criteria for listing as a prosthetic item.

Furthermore, they mentioned that there may be an opportunity for wastage in this category, by clinicians using more staple reloads than necessary, and the ability to confirm such wastage is limited through audit of clinical records.

Pricing and Categorisation of General Miscellaneous Items

03.02 – Drug Delivery Devices

It was noted by some private health insurers that there is significantly varied pricing among the infusion pumps within this category, however the types of pumps used are interchangeable, as there is minimal difference in clinical effectiveness and patient outcomes. One pointed out the inconsistencies between categories and the basis for pricing is not explicit for infusion pumps on the

PL, and claimed that private hospitals therefore have no incentive to be cost-conscious in their choice of device.

03.02.02 – Infusion Pumps, Balloon Based

One private health insurer identified that the costs of some items in the Fixed Flow Rate sub-group have seen significant fluctuations in costs without explanation. They also noted that several price increases occurred alongside the addition of the 'Set' suffix.

The private health insurer reported that prior to the price increase, the total cost of a patient requiring 28 days of antibiotics for a post-operative infection would have been $9,044, but now the total cost is $13,104, representing a 45% increase. They claimed this increase may impact their ability to provide members with their preferred choice of treatment as there will be an element of financial consideration to funding requests.

In their feedback, they also referred to the devices in this sub-group with the higher benefit of $224 have the suffix 'Set', which they state should apply when the accessories and consumables are supplied together with the infusion pump. This private health insurer maintains that there are currently 9 billing codes in this sub-grouping with the 'Set' suffix, but the description on the PL is not comprehensive about which components or products are included in the set. Therefore, the details of what is or is not included in the 'Set' is not transparent to paying stakeholders.

Another private health insurer mentioned that applications for devices to be re-classified or re-grouped to a pre-existing 'Set' suffix does not involve as thorough and scrupulous process as the initial application for the creation of an entirely new suffix. If the applicant device is sufficiently equivalent to comparators, a recommendation is made to the PLAC without a detailed economic assessment of relative clinical benefit.

03.05 – Haemostatic Devices

One manufacturer suggested that the categorisation of Haemostatic Devices could be split between active and passive to reflect the role they have in blood management in a clinical setting.

03.05.05 – Matrix

Anomalies were identified by one manufacturer on the PL related to the product size and relative value of Matrix haemostatic devices. They communicated that under the current listing arrangements, insurers could be paying the same reimbursement for an 8mL and a 10mL vial. For a categorisation that more accurately reflects relative value within this category, they suggested products could be categorised and priced based on their active ingredients, and per mL of their active ingredient, rather than the arbitrary size split of <=6mL and >6mL.

It was noted in clinical input that marketing has contributed to the increase in the use of Thrombin products; however, it does not appear to show clinical superiority, and is only necessary for patients with low Thrombin states. For the general population, the Thrombin component is not necessary, and there is evidence to suggest the usage of Thrombin products may even transmit viral diseases, cause allergic reactions, or cause the patient to develop antibodies. Therefore, a Health Technology Assessment could be appropriate for these products to assess the benefit value relative to clinical superiority.

03.05.06 – Foam

A private health insurer and a private hospital group both said that a box of eight Foam products costs $1,136 on the PL ($142 per unit). In comparison, the same products are listed through the NHS

at £25.65 GBP per unit. Members of the public can also purchase a box of eight though an online retailer for $99 USD.

03.06 – Luminal Stents

Two manufacturers suggested in their feedback that products within the Luminal Stents category could be moved to another category on the PL for the related surgical specialty if there is a concern that the '03 – GM category' is too broad. For example, '03.06.01 – Biliary Stents' could be moved to the '10 – Vascular' product category. Alternatively, they could be re-classified under a new 'Digestive System' category.

03.08 – Closure Devices

03.08.01 – Adhesion Barriers

There was feedback from some medical device manufacturers that some products within this group are used in specific surgical specialties. For example, they referred to one product that is used in the spinal surgical specialty. Therefore, they suggested that if it were to remain listed on the PL, it could be moved to the '13 – Spinal' category.

03.08.02 – Internal Adhesives

One manufacturer identified that there is inconsistency in the pricing within the Internal Adhesives group, as some of the products that are labelled as topical skin adhesives attract the same rebate price as surgical adhesives, when they are not clinically comparable. There have also been price increases in some of the sub-groups. One private health insurer communicated that a series of changes to product listings and price points appears to be a strategy by manufacturers to capture higher benefit amounts without any changes to the product itself.

One manufacturer notes that the presence of one Internal Adhesive product on the PL has meant that clinicians have often replaced a $15 foil covered under hospital arrangements, with at least one or more $1,443 PL products per patient. For instance, one private hospital group reported an isolated example where more than $10,000 was billed for a PL-listed skin closure product for a single patient undergoing a knee replacement. As such, it is suggested by stakeholders that the list is becoming a tool to optimise revenue from adding the item to every procedure, whether there is any clinical cost effectiveness evidence.

Moreover, a manufacturer and a private health insurer both identify that one Internal Adhesive product is listed twice on the PL, appearing both in the Internal Adhesives category on the 03 – GM list, as well as the Dura Defect Repair category on the '04 – Neurosurgical' list. According to these stakeholders, the selection of two different groups for these listed products by would appear commercially motivated by the sponsor, with Dura Defect Repair attracting higher reimbursement for the smaller sizes than Internal Adhesives.

One manufacturer suggested that if Internal Adhesives were to be removed or decreased in price from the GM category of the PL, other suppliers in turn may use the Dura Defect Repair codes to list their own products under comparator status, effectively moving the issues of appropriateness for listing between the list categories.

One private health insurer provided feedback that the 'Rigid Delivery System' suffix was introduced in August 2014, with the benefit amount of $160. Since then, total benefits paid for this category has risen over the past five years, almost in line with volume. They noted movements for several products from the 'Extender' suffix into the 'Rigid Delivery System'. They state that in all these cases of re-classification, there was an almost 400% increase in the benefit level per-item, from $31 to

$160, with no material change to the product descriptions and no evidence of what had been added to form the 'system'.

03.08.03 – Ligating Devices

One manufacturer suggested that products within the '03.08.03 – Ligating Devices' and '03.08.04 – Staples & Tackers' groups could be recategorized into a new product group 'Gastrointestinal System' to better reflect distinct surgical specialties.

03.08.05 – Polypropylene / Polyester Mesh

Some medical device manufacturers identified that this category contains many innovative mesh products that are used in the hernia surgical specialty, which does not currently have its own specific category within the PL. Therefore, they suggested it may be more appropriate to establish an additional product category called 'Hernia' to incorporate relevant products within the 03.08.05 – Polypropylene / Polyester Mesh, 03.08.06 – Composite Mesh, 03.08.07 – Complete Biomaterial Mesh, 03.08.08 – PTFE / ePTFE Mesh and 03.08.09 – Plugs groups.

Alternatively, one suggested that the Closure Device category may be more appropriately defined as 'Soft Tissue Reinforcement and Soft Tissue Repair', to encompass not only products involved in a hernia repair, but also prosthetic implants that are involved in anastomotic reinforcement procedures. One private hospital group communicated that the creation of a new category or product group should be done in consultation with sub-specialists in the relevant areas and could further assist the investigation on the use and application of devices within these categories.

Unintended consequences of product removal

Patients Left Out of Pocket

There was a widespread sentiment across all stakeholders that removing items from the PL may cause a cost-shift with the burden to fall on patients, as private hospitals may need to rely on alternative arrangements where out-of-pocket gaps for non-reimbursed costs can be charged and passed onto the patient. Several stakeholders raised the concern that if private hospitals are not willing to absorb these costs and the products cannot be funded through other mechanisms, any items that are removed from the PL would cause a disadvantage to patients.

Diminished Access to Devices

Several stakeholders also commented that while patients should be able to access the best medical devices necessary for their treatment, removal of items from the PL may have a detrimental impact on patient outcomes due to limited device selection. One private hospital group noted that where hospitals deem it unsustainable to continue providing these items or patients are unwilling or unable to pay for them, a clinician's access to these items could become restricted, and they may be forced to select products that they deem inferior to the most clinically appropriate option for their patient. Therefore, they suggested that in the case that a hospital cannot make the appropriate technology available because it is not on the PL, patients may not receive the best clinical product required for their condition and care.

Cost Burden on Hospitals

There was feedback across all stakeholder groups that hospitals may be placed under financial pressure without proper transition arrangements for alternative funding. One private hospital group raised a concern that some hospitals already have contractual arrangements in place that prohibit the passing of out-of-pocket expense charges to patients. This means that removing items from the list that could not be appropriately funded through other mechanisms may lead to the burden for

payment falling on private hospitals. In particular, another group commented that smaller hospitals have limited negotiating leverage with private health insurers, making it harder for them to negotiate viable Hospital Purchaser-Provider Agreements (HPPAs) and threatening the closure of some hospitals.

Patients Forced into the Public System

Several Private Hospital stakeholders indicated that some procedures may become commercially unsustainable in some private hospitals and they may cease to offer these services. For instance, one noted that bariatric surgery and laparoscopic gynaecology procedures typically have low margins. As such, they suggested patients could be forced to access such treatments through the public system, with potential expansion of public hospital waiting lists.

Administrative Upheaval

There was feedback raised across all stakeholder groups that the removal of items from the PL will prompt a complex, resource intensive and lengthy process of adjustment brought about by the necessity of hospitals and health insurers needing to negotiate alternative funding arrangements for episode payments. Several Private Health Insurers communicated that many companies in their industry in Australia are currently not contracted with a considerable proportion of private hospitals. They suggest that new arrangements may require months of implementation to allow for operational adjustments by private hospitals and clinicians, and to allow for sufficient time to determine a funding methodology that will not negatively impact patients or private hospitals.

There was widespread commentary from stakeholders that the National Procedure Banding Committee (NPBC) will also need to revisit the National Procedure Banding Schedule (NPBS) of individual Medicare Benefit Schedule (MBS) items so case payments could accommodate these devices and patient access would be maintained. One private hospital group suggested that any delays arising from the arrangement adjustments mentioned above may impact on the timeliness of patient care.

Breach of MTAA Agreement

Some medical device manufacturers communicated that if removal of products from the PL occurs prior to the expiry of the MTAA Agreement on 31 January 2022, it could be considered a breach of the Government's commitment to 'making no other changes on the Prostheses List during the term of this Agreement without agreement with the MTAA on behalf of the industry'. One commented that this would potentially jeopardise the relationship that exists between the Australian Government and the device sector and put at risk the integrity of all current and future agreements.

Contradictions in Other PL Category Listings

Some private health insurers commented that the basis for removal of some items may yield anomalies in the listing criteria for other categories on the PL. Therefore, they suggest the rationalisation needs consistent language and clinical indications if it is to set a precedent for reviews of other categories.

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