Members Health
FUND ALLIANCE

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Re: REVIEW OF THE GENERAL MISCELLANEOUS CATEGORY ON THE PROSTHESES LIST

On behalf of the health funds that make up Members Health and the Australian Health Services Alliance, please find our preliminary submission to the Department of Health's consultation for the *Review of the General Miscellaneous Category of the Prostheses List* (the List), released 3 February.

We thank the Department for extending the consultation period to provide all interested parties a greater opportunity to provide a response. Members Health and AHSA look forward to ongoing engagement with the Department and EY on this consultation, which concerns an issue of particular interest to our memberships.

From the outset, we wish to advise that the questions listed in the initial consultation circular have been addressed in the following studies undertaken by our two organisations in late 2019. The studies provide an illustrative sampling of the breadth and variety of adverse micro-economic effects that result from listing of items in the *General Miscellaneous Category* of the Prostheses List. The overarching conclusion of these studies is that there is significant evidence of commercial gaming in the *General Miscellaneous Category* of the List by certain medical device manufacturers.

This gaming includes vast volume and subsequent cost increases manipulated by medical device manufacturers, as well as questionable bundling of items to attract higher listing prices. The below analyses point to the likelihood that some medical devices firms are trying to circumvent cost reduction measures introduced by the Minister for Health in 2017 by encouraging use of (usually more costly) listed devices without evidence of better clinical outcomes, or by designing item 'bundles' with a premium price-tag. This behaviour illustrates the ongoing and growing economic inefficiencies arising from listing of many general use items in the *General Miscellaneous Category* of the Prostheses List.

It is important to reiterate that Members Health and AHSA commend the Minister for Health and the Department's commitment to the sustainability of Australia's private health insurance system, and benefit reduction measures on the List. We welcome this review as the latest step in that process.

However, we are concerned that this gaming and resultant growing cost inefficiencies to insurers (and consumers) has continued to occur despite medical device makers' pledge to promote the sustainability of private health care, to help keep PHI affordable, and improve value for all Australians[1].

Thus, we are strongly of the view that the whole of the *General Miscellaneous Category* of the Prostheses List should be removed from the Prostheses List to facilitate the re-establishment of commercial and cost disciplines and for the system to access resultant efficiencies. Existing funding

[1] Agreement between the Government and the Medical Technology Association of Australia (MTAA) - https://www1.health.gov.au/internet/main/publishing.nsf/Content/EE9D7DA6EA42BDE0CA257BF00020623C/$File/Attachment%20to%20MTAA%20letter%20-%20agreement.pdf

structures and mechanisms between funds and providers will ensure patients will not be left with additional out-of-pocket charges from providers with our requested change to the Prostheses List.

Beyond *General Miscellaneous* category, further reviews are also needed into other groups and sub-groups on the List. System and cost inefficiencies observed in *General Miscellaneous* have also been identified in other item categories, and therefore require the attention of the Department and industry consultation. A list of these additional categories has been included in Part 4 of this submission.

The List was established to regulate high-cost, procedure- or condition-specific or low-volume implantable devices, such as pacemakers and artificial hips. It was never the intention of the List to cover low cost or bulk, general-use and disposable items where there exists strong market competition and choice.

Sincerely

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1. MARGINAL CUTS IN PROSTHESES BENEFITS

In early 2018, the Commonwealth Department of Health, the Minister and the medical device industry provided to explicit assurances that they would deliver significant and sustained cuts to the cost of prostheses.

The Agreement between the Government and the Medical Technology Association of Australia stated:

> *The compact commits to maintaining Prostheses List benefits for a period of four years and implements process improvements by:*
> - *reducing prostheses benefits by $1.1 billion over four years with the savings passed on in full to consumers*

Rightly, health insurers anticipated that the pact would deliver savings of around $275 million per year, translating to a 13 per cent decrease on 2017-18 prostheses benefit levels, as per the below figures. And at 1 April in both 2019 and 2020, health funds delivered the lowest premium increases seen in decades.

APRA data, however, has shown that the savings promised by the Commonwealth Department of Health and device makers have simply not materialised. Instead, the private health insurers have seen marginal $13 million decrease in hospital treatment prostheses benefits since the Agreement was signed between the Government and the Medical Technology Association of Australia.

	2014-15	2015-16	2016-17	2017-18	2018-19
Total Hospital Treatment Prostheses Benefits Paid ($'000)	$1,894,466.15	$1,995,835.68	$2,091,490.46	$2,094,445.69	$2,081,061.66
$ Change YOY	$155,468.25	$101,369.52	$95,654.79	$2,955.22	-$13,384.03
% Change YOY	8.94%	5.35%	4.79%	0.14%	-0.64%

Source: APRA Operations of PHIs

Examining the exact cause of these increases, it became clear to Members Health and the Australian Health Services Alliance that the prostheses volume growth has occurred largely within low cost items. The two studies below provide glaring examples of device companies' circumventing the cost cutting measures promised in the Agreement.

Together, they provide further evidence to support the objectives put forward in the Review of the General Miscellaneous Category of the Prostheses List.

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2. VOLUME AND COST INCREASES ON THE LIST

Our analysis below of benefits paid by health funds in the Australian Health Services Alliance provides further evidence to support further reforms of the List, in particular, the removal low-cost items to arrest perverse outcomes, such as double payments and overutilisation and waste.

To illustrate, Members Health has identified significant product increases within the sub-category of Closure Devices, particularly Internal Adhesives and Staples and Tackers groupings. One glaring example is Johnson & Johnson adhesives for surgical skin closure, which have seen volume rises up to 500 per cent.

Internal Adhesives

Among AHSA health funds, the PL product grouping 'Internal Adhesives' – under sub-category Closure Devices – has seen an overall 129 per cent increase in volume and a 56 per cent increase in benefits paid over the past year. Within the product grouping, there have been particularly high increases in some sub-groupings.

AHSA volume – selected component categories of 'internal adhesives'

Internal Adhesives	FY18 volume	FY19 volume	Change	% change
03.08.02.01 - Adhesive ≤2ml	5777	24525	18748	324.5%
03.08.02.04 - Adhesive Accessory	4557	5460	903	19.8%
03.08.02.03 - Adhesive >5ml	1619	2165	546	33.7%
03.08.02.02 - Adhesive >2-5ml	2440	2489	49	2.0%

AHSA benefits paid – selected component categories of 'internal adhesives'

Internal Adhesives	FY18 volume	FY19 volume	Change	% change
03.08.02.01 - Adhesive ≤2ml	$1,192,197	$3,921,141	$2,728,944	228.9%
03.08.02.04 - Adhesive Accessory	$515,228	$604,886	$89,658	17.4%
03.08.02.03 - Adhesive >5ml	$2,094,923	$2,692,875	$597,952	28.5%
03.08.02.02 - Adhesive >2-5ml	$1,656,910	$1,589,951	-$66,959	-4.0%

AHSA volume – selected prostheses from '03.08.02.01 – Adhesive <= 2ml'

Adhesive ≤2ml	Prosthesis name	Sponsor	FY18 volume	FY19 volume	Change	% change
MN229	Dermabond	J&J	1798	9881	8083	450%
MN230	Dermabond Prineo	J&J	1585	9599	8014	506%
MI286	LiquiBand® Exceed™	Medtronic		1274	1274	
SQ124	INDERMIL Flexifuze	Surgical Specialties	440	971	531	121%
LH596	Liquiband Surgical	Lifehealthcare		497	497	

AHSA benefits paid – selected prostheses from '03.08.02.01 – Adhesive <= 2ml'

Adhesive ≤2ml	Prosthesis name	Sponsor	FY18 volume	FY19 volume	Change	% change
MN229	Dermabond	J&J	$80,910	$443,070	$362,160	448%
MN230	Dermabond Prineo	J&J	$442,176	$2,656,490	$2,214,314	501%
MI286	LiquiBand® Exceed™	Medtronic	$0	$57,240	$57,240	
SQ124	INDERMIL Flexifuze	Surgical Specialties	$21,330	$43,425	$22,095	104%
LH596	Liquiband Surgical	Lifehealthcare	$0	$22,365	$22,365	

Analysis

Johnson & Johnson's Dermabond, with a benefit level of $45, has seen volume and PHI benefit increases of 450 per cent in 2019, compared with 2018. Dermabond Prineo, with a benefit level of $277, has seen volume and benefit increases of more than 500 per cent.

Published evidence indicates the benefit from the use of skin adhesives over sutures is solely cosmetic or related to a shorter time to close wounds (a matter of only a few minutes). There is no clear indication of superiority of skin adhesives for surgical wounds when it comes to complication rates (wound infection, wound dehiscence [breakdown]).

Dermabond and Dermabond Prineo had been registered on the Australian Register of Therapeutic Goods (ARTG) and used widely for several years prior to PL listing in February 2018. The FY18 to FY19 volume growth data, therefore, demonstrates how PL listing has brought significant volume increases.

Prior to being listed on the PL, these items had to compete with skin closure alternatives (e.g., combinations of sutures, skin staples and adhesive and non-adhesive dressings). Consumables such as sutures, skin staples and adhesive/non-adhesive dressings are considered 'bundled' in funding arrangements with providers (whether such 'bundles' reside within 'theatre band' charges, DRG-based/non-DRG-based case or other forms of bundle payments, and other funding structures).

Historically through to the present, such funding arrangements have not specified in itemised and named detail, consumables and disposables that are used in general surgical skin closure. It would not be practical to do so. Thus, commercial cost disciplines applied by a provider and clinical discipline applied by medical practitioners would help ensure that surgical skin closure was undertaken by the most clinically effective and cost efficient manner (with no resultant out-of-pocket for patients).

However, with PL-listing of the likes of Dermabond and Dermabond Prineo, cost disciplines were removed. As PL-listed devices are, in effect, directly funded in an uncapped manner by insurers, hospitals (aided by device sponsors) were incentivised to increase utilisation of the PL-listed devices and in so doing, reduce expenditure on non-PL listed consumables.

Per procedure, insurers therefore pay more for related to skin closure consumables, hospitals reduce their expenses, and device sponsors receive more revenue.

These micro-economic effects reverberate through most of the product sub-categories and groups of the *General Miscellaneous Category* of the Prostheses List

Evicel

Evicel and Tisseel are both fibrin sealants used across a variety of procedures, but largely to arrest bleeding during surgery. They both have the same two main components – 'sealer protein' with an active agent that is fibrinogen; and thrombin – and come in 2ml, 4ml and 10ml formulations.

AHSA volume – selected prostheses from '03.08.02.03 – Adhesive > 5ml'

Adhesive >5ml	Prosthesis name	Sponsor	FY18 volume	FY19 volume	Change	% change
MN204	Evicel Solutions for Fibrin Sealant (10ml kit)	J&J	504	1132	628	125%
BX254	CoSeal Surgical Sealant	Baxter	454	435	-19	-4%
BX216	TISSEEL Two Component Fibrin Sealant Syringe	Baxter	584	518	-66	-11%

AHSA benefits paid – selected prostheses from '03.08.02.03 – Adhesive > 5ml'

Adhesive >5ml	Prosthesis name	Sponsor	FY18 volume	FY19 volume	Change	% change
MN204	Evicel Solutions for Fibrin Sealant (10ml)	J&J	$690,060	$1,465,933	$775,873	112%
BX254	CoSeal Surgical Sealant	Baxter	$498,363	$450,164	-$48,199	-10%
BX216	TISSEEL Two Component Fibrin Sealant Syringe	Baxter	$800,464	$673,099	-$127,365	-16%

Analysis

First listed on the PL in February 2013, Evicel's 4ml and 10ml formulations (MN151 and MN152) had listed PL benefits of $1,000 and $700 respectively. However, in February 2017, additional listings were created for Evicel:

MN202: a 2ml formulation with a PL benefit of $800 - $100 higher than the 4ml MN151;

MN203: a 4ml formulation with a PL benefit of $835 - $135 higher than the 4ml MN151; and,

MN204: a 10ml formulation with a PL benefit of $1,400 - $400 higher than the 10ml MN152.

Six months later, by the August 2017 Prostheses List, J&J had removed MN151 and MN152 from the PL. By 30 June 2019, volumes for the 10ml Evicel formulation had risen more than 125 per cent.

Additionally, Evicel-related items within the PL sub-group of 'Adhesive Accessory', saw corresponding increases – up 146 per cent in utilisation and 132 per cent in benefit cost.

This series of changes to Evicel listings and pricing points to a strategy by J&J to capture higher PL benefit amounts for their Evicel formulations without any changes to the actual product itself.

Tisseel formulations have been listed on the PL for over 15 years, and have seen stable volume increases from FY18 to FY19.

Additionally, the mix of utilisation of Tisseel across its three volume formulations has been stable with about 23 per cent, 61 per cent and 16 per cent for its 2ml, 4ml and 10ml formulations respectively over several years. In contrast, Evicel's mix of utilisation in FY19 was 0 per cent, 19 per cent and 81 per cent for its 2ml, 4ml and 10ml formulations. In FY18, Evicel's mix of utilisation was 0 per cent, 30 per cent and 70 per cent for its 2ml, 4ml and 10ml formulations.

It is clear that increased utilisation of Evicel's 10ml formulation has been encouraged. Given the clinical applicability of Evicel and Tisseel are identical, it can only be assumed that the increased use of 10ml formulations of Evicel has resulted in significant waste.

It should be noted that such waste cannot be identified/confirmed by auditing clinical records. Due to legislative obligations placed on insurers by PL-listing, such waste and resultant inefficiencies will continue. Furthermore, in general, all PL product sub-groups structured in size- or volume-based tiers are exposed to gaming with waste.

The micro-economic levers that may otherwise be in effect to retain cost disciplines by limiting waste and applying more discretionary use of 'accessory' products are removed due to PL-listing.

Staples and Tackers

In the product grouping of 'Staples, Non-bone with Disposable Applier' and 'Staples, Non-bone (Reload)' – both under the PL sub-category of Closure Devices – we note volume and benefit increases.

AHSA volume – selected sub-groups from '03.08.04 – Staples & Tackers'

Staples & Tackers	FY18 volume	FY19 volume	Change	% change
03.08.04.04 - Staples, Non-bone with Disposable Applier	3760	7313	3553	94%
03.08.04.01 - Staples, Non-bone (Reload)	27981	31238	3257	12%
03.08.04.03 - Staples, Reinforcer	9337	10403	1066	11%
03.08.04.02 - Staplers	5952	6579	627	11%

AHSA benefits paid – selected sub-groups from '03.08.04 – Staples & Tackers'

Staples & Tackers	FY18 volume	FY19 volume	Change	% change
03.08.04.04 - Staples, Non-bone with Disposable Applier	$1,835,852	$1,861,359	$25,507	1%
03.08.04.01 - Staples, Non-bone (Reload)	$9,861,245	$10,480,221	$618,976	6%
03.08.04.03 - Staples, Reinforcer	$3,295,545	$3,458,128	$162,583	5%
03.08.04.02 - Staplers	$2,508,840	$2,692,905	$184,065	7%

AHSA volume – selected prostheses from '03.08.04.04 – Staples, Non-bone with Disposable Applier'

Staples, Non-bone with Disposable Applier	Prosthesis name	Sponsor	FY18 volume	FY19 volume	Change
MN237	Stratafix	J&J	0	3,592	3,592

AHSA benefits paid – selected prostheses from '03.08.04.04 – Staples, Non-bone with Disposable Applier'

Staples, Non-bone with Disposable Applier	Prosthesis name	Sponsor	FY18 volume	FY19 volume	Change
MN237	Stratafix	J&J	$0	$154,012	$154,012

Analysis

Data suggests increases have been caused primarily by the inclusion of Stratafix (MN237), with the remaining devices in the group retaining in aggregate flat volumes from FY18 to FY19.

Unlike others in the sub-group, Stratafix is not a stapler device. It is a barbed suture used in closure of surgical wounds, which has been available for years and should not have been listed on the PL. Though Stratafix has recently been removed from the PL, the effects of PL-listing this item illustrates the perverse micro-economic effects it triggers and the resultant rapid introduction of inefficiencies and other distortionary effects.

From its first listing on the PL in March 2019 for $43, volumes for the item were significant, recording 3,592 utilisations at a cost of $154,012 in just three months.

This increase was the result of two micro-economic effects in force:

Where Stratafix had previously been used in surgery, it would have been accounted for as part of the funding amounts rendered by insurers to private hospitals (bundled in theatre charges, case payments or DRG-based funding structures). Following PL listing, this funding shifted without an offsetting adjustment to insurers' payment structures to private hospitals.

As Stratafix became the first and only suture listed on the PL, it can be suggested that there has been a concerted push by J&J for the product to be used in procedures instead of other, cheaper alternatives, such as standard sutures or skin clips as well as competitor sutures with similar clinical effects.

Prices for standard sutures used in skin can vary. However, in general, purchases in large quantities can achieve significant discounts – between $8 and $24 per unit.

If not for the introduction of Stratafix, benefit reductions applied to this sub-group under the MTAA agreement would have indeed resulted in a net reduction in benefit outlays from FY18 to FY19.

As for the other devices listed in the 'staples' product sub-groups, many are used in various types of bowel surgery (to excise bowel, create bowel anastomoses, etc.) and they do substitute for alternative approaches (e.g. using sutures to create bowel anastomoses). As noted above, volume growth for these devices has been in excess of 10 per cent year on year.

Due to PL-listing, the micro-economic bias results in a greater propensity to use PL-listed 'staples' in preference of alternative approaches. Furthermore, the opportunity to waste, that is to use more staple reloads than otherwise necessary, is higher. As with Evicel, the ability to confirm such wastage is limited through audit of clinical records.

Summary conclusion on Volume and Cost Increases

Prior to the above products being included on the prostheses list, utilisation of such low-cost, general use or bulk items would have been constrained by private hospitals' mindful and prudent cost management under market based funding arrangements with insurers. However, the data suggests that adding these items to the Government controlled PL eliminates competitive tension and the need for hospitals to maintain a fiscally prudent business approach to their use and cost.

The listing of Dermabond products on the PL, provides a compelling example of the inflationary impact of current regulation, which is being gamed by hospital operators and the medical device industry for financial gain and is contrary to the public interest. As long as items such as adhesive skin closure devices are listed on the PL, substitution and excessive volume growth is expected to continue, placing further pressure on health insurance premiums and damaging affordability for consumers.

The removal of low cost, general use or bulk items from the PL, will deliver superior outcomes for consumers. Deregulation will incentivise clinical and economically prudential adoption and use of newer technologies under hospitals' own micro-economic controls – especially as these services fall under existing hospital funding frameworks.

It should be noted that the examples provided above are but a few of many under the 'General Miscellaneous' category, where perverse micro-economic effects have been allowed to take root due to regulatory failure. Similar effects can be seen in sub-categories such as 'drug delivery devices', 'haemostatic devices' and other 'closure devices'.

We encourage the Department of Health to undertake a wide and forensic examination of the 'General Miscellaneous' category, and its sub-categories, with a view to removing all low-cost and bulk items and in particular, disposable items from the PL. The PL was only ever supposed to deal with high cost low volume prostheses and the inclusion of low-cost, general use and bulk items represents an extension of the PL beyond its intent and is contrary to the public interest.

3. GAMING OF BUNDLE CATEGORIES - PROSTHESES LIST

Evidence below demonstrates that some device companies are actively exploiting the allowance of "set" or "systems" suffixes on the list by transforming single-item prostheses into bundles of far higher cost, yet questionable value.

Members Health does not question the legitimacy of allowing bundles on the List, understanding that some prostheses require specifically tailored accessories or additional parts to ensure their effective clinical use. The concern, however, is that due to regulatory failure, the allowance of "set" or "systems" suffixes is being gamed to drive up revenue for device companies and that this is placing an unfair financial burden on consumers and Government and is against the public interest.

The process of creating a "set"

The creation of an entirely new "set" or "system" suffix/sub-group on the Prostheses List is triggered by an application for a new device listing. The applicant (device sponsor) argues the case for the creation of the suffix/sub-group bundle and describes the contents of their application.

The Department of Health and clinicians from the relevant Prostheses List Clinical Advisory Group (CAG) or Panel of Clinical Experts then assess the application, and provide their opinions to the Prostheses List Advisory Committee.

PLAC makes its determination on a recommendation for listing, usually accepting the opinions from the CAG or Panel of Clinical Experts, and rarely calls for the details of the device sponsor's application.

In creating entirely new "set" suffix/sub-groups, the PLAC has historically called for the Health Economics Sub-Committee (HESC) to assess the requested benefit amounts, with its recommendation then also considered. Since HESC's replacement with a Health Technology Assessment (HTA) process, PLAC has had to reconsider whether to refer applications to a HTA process.

This HTA process provides an important additional layer of scrutiny.

Applications for devices to be re-classified or re-grouped to a pre-existing "set" or "system" suffix/sub-group, involves a much less thorough and scrupulous process to that set out above.

Applicants must provide the details of their product re-classification to the Department of Health, then it is assessed by the relevant CAG or Panel of Clinical Experts against pre-existing comparators in the relevant suffix/sub-group. If the applicant device is sufficiently equivalent to comparators, a recommendation to list is usually made by the PLAC without any further detailed economic assessment.

<u>There is no need for a benefit determination step as there is a pre-existing suffix/sub-group. Members Health suggests it is this re-classification or re-grouping process that is most at risk of gaming by device making firms.</u>

Overarching the issues in this process is the fact that subsequent to listing, the details of what constitutes a "set" (or any other listing on the PL) remains lost. The PL does not capture item detail beyond the PL billing code and general descriptors. Moreover, the details of what is or is not in the "set" is not transparent to health funds (nor other paying stakeholders).

Case Study 1: Baxter "Sets"

In the November 2019 Prostheses List, changes were submitted to the grouping of five Baxter devices. The five devices carry the PL codes BX247, BX281, BX287, BX327 and BX328.

In the July 2019 PL, these devices were all listed without the "Set" suffix for a benefit amount of $79 in the product sub-group 03.02.02.01 – *Fixed Flow rate product group 03.02.02 – Infusion Pumps, Balloon Based*.

But come the November 2019 list, these devices had been moved to the 03.02.02.01 – Fixed Flow rate sub-group with the suffix "Set". In so doing, the PL benefit amount increased from $79 to $241.

The description of what is additionally included in the Baxter "set" for all those five devices is a Government secret, has not been disclosed to payers and is not transparent. As noted in the table in Appendix A, the item descriptors and sizes remained identical in the November 2019 PL as the July PL.

Echoing the points made in our previous October 2019 correspondence regarding removal of all *General Miscellaneous* devices and low-cost items from the PL, Members Health strongly suggests Baxter is gaming the PL for financial gain against the public interest and that there is regulatory failure that must be addressed as a priority by Government.

Baxter's manipulation of the regulatory process has directly resulted in the transfer of funding of consumables such as IV tubing from insurer-provider agreements to PL funding, at an exorbitant increase in benefit without relative clinical benefit. It also results in the substitution of use of alternative devices that would otherwise be covered by insurer-provider agreements.

Product	Total AHSA Benefits FY2015	Total AHSA Benefits FY2019	4 Year Change in AHSA Benefits
Baxter Folfusor	$101,745	$155,436	53%
Baxter Infusor	$254,405	$321,423	26%
Baxter Dosi-Fuser	$18,550	$41,623	124%

Case Study 2: Rigid Delivery Systems

Significant benefit expenditure growth has been identified in the re-classification of devices into "systems" in the 03.08.02.04 category – *General miscellaneous, closure devices, internal adhesives with the suffix 'Rigid Delivery System'*.

Appendix A – Sheet 2 presents five glaring examples of large multinational profit driven prostheses companies re-classifying their items as "systems" in order to increase revenue on the items against the public interest.

The "Rigid Delivery System" suffix was introduced in August 2014 with the first such product – Matrix Surgical's Glubran 2 Rigid Spray Device (MG044), with a benefit amount of $160. Appendix A data shows the per-item benefit has remained stable, while total AHSA paid benefits have risen over the past five years almost in line with volume.

However, Baxter moved three of their products (BX265, BX267, and BX273) from "Extender" into the "Rigid Delivery System" group in February 2016. J&J followed with two of their products (MN041 and MN153) in February 2017.

In all five examples of Baxter and J&J re-classification, there was a four-fold 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".

Total AHSA benefits paid over the past five years for these items paints a clear picture of how re-classification these products as "systems" can be a very profitable move for the device making companies. The table below summarises the changes in volume vs benefits paid.

Product	Total AHSA Benefits FY2015	Total AHSA Benefits FY2019	4 Year Change in AHSA Benefits
Tisseel Duplotip with Snaplock 31.8cm & 40cm	$3,193	$22,976	620%
Tisseel Duplospray MIS with Snaplock Applicator 40cm	$15,221	$92,178	506%
Floseal Endoscopic Applicator	$16,988	$136,636	704%
Endoscopic Applicator	$5,363	$78,710	1368%
Evicel rigid tip applicators	$775	$173,426	22278%
Comparison			
*Glubran 2 Spray Device	$8,960	$23,712	165%

* Glubran 2 spray device was first listed in Aug 2014, the volume and benefits paid only cover part (but more than 50%) of the base year of FY15 used in the calculations.

Summary conclusion Prostheses List Bundling

There is unequivocal evidence of regulatory failure by the Department of Health that has facilitated the gaming of the PL by medical device companies - contrary to the public interest.

To address the gaming of "set" or "system" suffix/sub-grouping, Members Health suggests PL applications to these categories should attract appropriate scrutiny from both the Department of Health and the PLAC, particularly in cases of re-classification. We further suggest that these items be subject to transparency so that they can be scrutinised by payers, as is appropriate and as is consistent with the recommendations of the Lloyd Samson Review.

Noting that all applications ultimately funnel through PLAC and there are hundreds of applications during each PL cycle, it would be impractical to ask that PLAC assess every single application, as it would **a)** likely de-value or be perceived to devalue the contribution of clinicians from the CAGs and the Panel of Clinical Experts; and **b)** be an extremely time consuming and costly task.

Instead, we recommend two additional processes to provide assurance that "set" and "system" suffix applications and re-classifications are not exploited by device companies.

Bundling Recommendation 1:

The detail of what constitutes a "set" or "system" should be clearly defined and documented in the sponsor's application and made known to the reviewing clinicians. This would include product catalogue numbers and the like.

Currently, CAG or Panel members are provided with some detail of what is in the "set" from the applicant, but because they cannot view the details of already-listed comparator "sets", CAG or Panel members are left to assume that the applicant's "set" is comparable.

As such, we suggest clinicians be allowed and required to access the details of all existing comparator "sets" or "systems" on the PL, such that they are better informed when assessing new applications.

Bundling Recommendation 2:

Secondly, this detail should be made transparent on the PL – if not on the spreadsheet/data table that is published and made available to insurers, then through an online portal. This level of transparency would allow post-PL-listing verification of hospital claims by insurers should they wish to audit claims of "sets" or "systems".

We believe providing this level of transparency will limit inappropriate use of PL billing codes.

Further to the outlined exploitation of the structure of the Prostheses List demonstrated by the product sub-groups above, the utilisation pattern of PL-listed products such as 'infusion pumps' overall (which include the Baxter 'sets') and adjunct devices such as 'delivery systems' highlight another source of perverse micro-economic effects.

These products, in a creeping fashion, gradually substitute for devices that would otherwise have been expended by hospitals as capital items or consumables. For example, PL-listed infusion pumps and related 'sets' (all of which are not surgically implanted into patients) substitute for alternative means of intravenous infusion – such as use of i-Med pumps (capital, multi-patient-use devices) and related bags and tubing.

Such alternative means of intravenous infusion are included ('bundled') in current (and historical) funding for hospital accommodation (and theatre if applicable) services. The perverse micro-economic effects arising from PL-listing of infusion pumps and related 'sets' are similar to those described above for the Dermabond and Dermabond Prineo example.

4. ADDITIONAL CATEGORIES ON THE LIST NEEDING REVIEW

Other groups and sub-groups of items on the Prostheses List also, through listing, result in system inefficiencies similar to that observed in the *General Miscellaneous Category*. The following groups of items on the List therefore also require comprehensive review by the Department and stakeholders to ensure consumers pay a fair and efficient price for medical devices.

Category	Sub-category
Ophthalmic category	• Intraocular fluids • Lacrimal duct drainage prostheses • Retinal detachment prostheses
Ear, nose, throat category	• Ventilation tubes/grommets • Ear bone cement • Tracheal speaking valves and cannulae
Neurosurgical	• Aneurysm clips • Dura defect grafts and sealants • Intrathecal catheters and accessories • Extraventricular drains
Urogenital	• Ureteric stents • Tubal obstruction devices • Nephrostomy catheters
Specialist orthopaedic	• Bone cement • Bone graft substitute • Plates • Screws • Staples • Nails • Accessories
Plastic and reconstructive	• Biomodels
Vascular	• Vascular patches • Arterial closure devices • Long term vascular access devices • Peritoneal dialysis catheters