s 22

From: s 47F
Sent: Tuesday, 3 March 2020 4:04 PM
To: Prostheses Reform
Subject: Bupa Submission [SEC=No Protective Marking]
Attachments: PL Consultation GeneralMisc Bupa Submission.pdf

Categories: s 22

Hello,
Please find attached Bupa's submission to the current review on the General Miscellaneous category of the Prostheses List.
Please kindly note this submission is Commercial-in-Confidence.
Kind regards,

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Work days: Monday – Thursday

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Bupa Response

INPUT INTO THE REVIEW OF THE GENERAL MISCELLANEOUS CATEGORY OF THE PROSTHESES LIST

Bupa is pleased to respond to the Department of Health's review of the General Miscellaneous Category of the Prosthesis List.

Bupa has included responses to the requested questions. We have also included data demonstrating growth in the general item prosthesis list, other ways consumables are funded outside the list, and specific examples of items/devices which are not prosthesis but remain on the list under the General/Miscellaneous category.

Bupa strongly recommends the Department review this data and seek to remove inappropriate listings under the general miscellaneous category.

1. Are there any sub-categories or product groups/sub-groups within the General Miscellaneous Category that should not be included on the Prostheses List?

Bupa believes there are several items within the general miscellaneous category that should be removed.

Drug delivery devices

Bupa believes that except for the Insulin pump and accessories, all other drug delivery devices should be removed from the list as they can be used for multiple patients.

You will note in Bupa's data below, we have seen exponential growth in this category from $83,908 in 2017 to $491,068 in 2019, which is growth of 485% over this period.

Drug Delivery Devices - Benefits Paid And Services supplied by year for each item number

	2017		2018		2019		Total Sum of benefit	Total Sum of services
ITEM CODE	Sum of benefit	Sum of services	Sum of benefit	Sum of services	Sum of benefit	Sum of services		
FX003					$196,024	458	**$196,024**	**458**
FX004					$164,780	385	**$164,780**	**385**
MS066	$17,900	2	$51,372	6	$17,004	2	**$86,276**	**10**
RE001	$6,608	2	$1,000	5	$400	2	**$8,008**	**9**
SI034	$59,400	12	$109,242	23	$32,921	7	**$201,563**	**42**
SI045			$42,618	9	$51,722	11	**$94,340**	**20**
SI052					$28,217	6	**$28,217**	**6**
Grand Total	**$83,908**	**16**	**$204,232**	**43**	**$491,068**	**871**	**$779,208**	**930**
					$$ Growth from 2017 to 2019		**$407,160**	**485%**

Infusion pumps

Infusion pumps are commonly used to deliver medication and should be covered within the hospital admission diagnosis related grouping (DRG) as they are a standard tool used for certain episodes of care and can be used multiple times on different patients.

An example of this would include pumps used during the perioperative period to deliver pain relief or antibiotics.

Bupa would suggest the only acceptable exception to this would be any pumps used in chemotherapy treatment or insulin delivery. There are no implantable devices in this category (As above, specifically battery-operated devices) and no single use or single patient specific devices Included in the above items.

Bupa is aware that this category of items is ordered directly from a supply company and are reused many times on multiple patients.

Closure devices

Bupa recommends that any item that is not permanent and ongoing in its function should be removed, such as glues and other temporary consumable items.

This includes all items in the following categories:

03.08.01 - Adhesion Barriers and 03.08.02 - Internal Adhesives

The inclusion of adhesives is used commonly for general skin closure (as another layer of skin closure of ten used as well as sutures) and should be covered within the hospital admission DRG. Below is a chart with examples of these items, showing that from 2017 there was very nominal spend to a dramatic increase up to $3.177 million in 2018, which further increased to $4.376 million in 2019.

Closure Devices - Benefits Paid And Services supplied by year for each item number

	2017		2018		2019		Total Sum of benefit	Total Sum of services
ITEM CODE	Sum of benefit	Sum of services	Sum of benefit	Sum of services	Sum of benefit	Sum of services		
BB382					$45	1	**$45**	**1**
BB383			$1,099	25	$16,290	362	**$17,389**	**387**
BB394					$554	2	**$554**	**2**
BB395					$1,939	7	**$1,939**	**7**
LH596			$10,080	224	$53,730	1195	**$63,810**	**1419**
LH597					$4,934	22	**$4,934**	**22**
MG047					$270	6	**$270**	**6**
MI286			$31,500	701	$144,405	3209	**$175,905**	**3910**
MN229			$482,254	10720	$679,185	15097	**$1,161,439**	**25817**
MN230			$2,612,146	9343	$3,430,493	12393	**$6,042,639**	**21736**
SQ124	$6,600	124	$40,410	898	$44,775	995	**$91,785**	**2017**
Grand Total	**$6,600**	**124**	**$3,177,489**	**21911**	**$4,376,620**	**33289**	**$7,560,709**	**55324**
					$$ Growth from 2018 to 2019		$1,199,131	38%

*Note - growth is being measured from 2018 as virtually no activity in 2017

Haemostasis devices

Items in this category are meant to be used only under certain conditions – such as when conventional means of haemostatic control do not work. However, Bupa is finding they are being used as a regular surgical item. These items can range dramatically in price $9-$950 per item.

These items are also already negotiated as part of contracting arrangements. Bupa agreements with providers already have provisions as to how consumables are funded. Any growth in haemostasis devices show an increasing cost placed on Funds and it is essentially a double payment for the same item which should be considered part of a single procedure.

When Bupa enters into a contracting arrangement with a provider, contracts state that procedures within the hospital is all inclusive except for prosthesis and medical (doctor/specialist fee) costs. As such, consumables and devices used during any patient admission are considered bundled. For surgical procedures, these consumables will have been taken into account through setting a theatre band by the industry *National Procedure Banding Committee*. When a device is then added to the General Miscellaneous list, Bupa and consumers are paying twice - as certain device costs are already embedded in our agreed benefit with providers.

2. Would any of the sub-categories (or groups or sub-groups) within the General Miscellaneous Category of the Prostheses List be better listed elsewhere in the Prostheses List?

Bupa strongly believes that moving items (such as the examples presented in response to question one) to another part of the list will not solve the problem.

It is vital that the Department of Health act promptly to remove the inappropriate items that have been listed rather than move categories.

3. Are there any General Miscellaneous category items that were funded through non-Prostheses List arrangements prior to being listed on the Prostheses List?

In Situ

Bupa is aware of a growing trend of claiming for devices that do not remain *In Situ*. These devices are non-implantable and used in a surgical procedure as a guide (to cut or drill through) or to view (such as a bio model, a plastic model of the patient's anatomy disposed of at the end of the case). They are usually removed prior to surgery completion and disposed of.

In hospital contracting, Bupa agrees to only pay for devices that remain in the patient (implantable). The fact Bupa is seeing a growth in being billed for these items is a deliberate cost shift to Funds and not in line with the intention of items on the Prosthesis List.

It is important to note that within hospital agreements it is stated that if there is any consumable cost that this cost cannot be passed on to the customer. There is no advantage to the patient for

claiming these costs – it is only the supplier and hospital that benefit from any claim to an *In Situ* item.

Bupa is aware of many items that were used in procedures but not included on the Prosthesis List. As the General and Miscellaneous category has expanded, so have the costs to Funds.

Bupa recommends the Department consider that many of these items that currently exist on the list for this purpose should be considered as part of the procedure rather than a separate item on the list.

Other items

Although not within the General Miscellaneous category, Bupa wishes to highlight some examples of consumable claiming that echo the arguments stated above.

Cardiac Ablation Catheters

The addition of cardiac ablation catheters to the Prosthesis List is an inflationary cost for Health Funds. These devices are consumables, and Bupa Agreements with Hospitals already have provisions as to how consumables are funded.

Prior to the devices being listed on this list, there was no member out of pocket for these devices. Furthermore, the true cost of these devices has always been questionable as some financial models that hospitals/cardiologists had in place paid for the capital cost of the actual ablation machine via an inflated consumable cost.

Bupa should not be paying for any cost of capital equipment through inflated device pricing. When these devices were listed, the cost to Bupa increased materially in several Agreements, as they went from being funded with a contribution and balance of cost bundled at a much lower price than the listing price.

At the same time, the hospital cost did not increase so the hospitals have received increased revenue without any corresponding cost increase, which comes solely at the expense of health funds. When this is raised as an issue during Agreement renewals, hospitals simply state that the items are listed, and "Funds must pay". These devices need to be delisted to enable funds to revert to previous arrangements in place.

Funds are concerned the listing of Ablation devices will lead to the listing of other consumable devices that are already accounted for in the theatre banding process and lead to further inflation of claims costs without providers experiencing increased costs.

Off Label Use of Implanted Prosthesis

The TGA regulates therapeutic goods to ensure they are of high quality, safe to use and work as intended. Since the creation of the Commonwealth Prosthesis Benefits List in 2003, Bupa has relied

on the strength of the details of the Intended Purpose of the Australian Register of Therapeutic Goods (ARTG) to link implanted prosthesis usage to correct surgical treatments.

Bupa is becoming increasingly aware of devices being used beyond the intent and conditions in the TGA approval based on evidence of safety and efficacy that is a pre-requisite for prostheses listing. Further, Bupa has concerns that this 'off label' use effectively creates experimental use of such a device, as clinical and trial outcome data was unlikely to have been supplied relevant to the extended use at the time the application was completed by the supplier and assessment made by TGA.

The current situation takes away from the Australian public an ability to rely on this health technology assessment process, and by association, the health technology assessment framework overall. This is because devices, drugs and services supported by the Commonwealth should be accepted as being safe and effective as a minimum, but acceptance of off-label use negates the ability to rely on these listings.

Bupa has sought refunds from hospitals who have billed for utilisation of prosthesis which have been used in surgical operations which do not conform to the 'intended purpose' of the device as listed in the ARTG. Funds have the benefit of having visibility of hospital claims data and medical claims data for the same customer. Linking this data provided a complete claims history for each hospital episode.

However, since December 2019, Hospitals and Medical Device Sponsors are resisting our requests for refunds where we can show that Intended Purpose is not met by the usage of the Medical Benefits Schedule number. This issue could be easily addressed in the listing process by putting in appropriate conditions in relation to the provision of listed prostheses. For instance, by ensuring the specific body part or condition of use in the TGA or MBS listing is granted, extended to and documented in the prosthesis list. Currently this field is rarely completed.

Bupa recommends that the Department seek to action and link Intended Purpose to the Conditions Column of the Prosthesis List and update legislation accordingly to reflect the usage of Prosthesis on the list be under the Therapeutic Goods Act.

Cosmetic items

Bupa is also aware of a growth in cosmetic items being claimed through the Prosthesis List.

The main example of this relates to dental implants, which are largely used for cosmetic reasons. The only situation where these items should be claimed as part of the General Miscellaneous category would be in the cases for mandible and auxilia (jaw) cancer.

Bupa would be happy to provide more information on these items if it is of interest to the Department.