s 22

From: s 47F
Sent: Wednesday, 11 December 2019 12:39 PM
To: PLAC
Cc: s 47F ; s 22

Subject: PLAC meeting [SEC=No Protective Marking]
Attachments: 20191211 RD to PLAC re meeting issues.pdf

Categories: Filed to TRIM

Dear s 47F ,

Please find attached our letter in relation to the PLAC meeting.

Kind regards,

s 47F

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11th December 2019

s 47F
Chair
Prostheses List Advisory Committee
Via email

Dear s 47F ,

I write regarding the Prostheses List Advisory Committee (PLAC) meeting this week. Private Healthcare Australia (PHA) has gone through the meeting papers, and I thought it would be helpful to outline in writing some of the issues our representative, Mr Moy, will likely raise at the meeting.

I would be happy for the tables to be distributed on a without-prejudice basis and not for further distribution if you feel it would aid the meeting.

Yours sincerely

s 47F

Agenda item 6.1 new listings

Item	Comment	Rec
N001687 – ITRACK SURGICAL SYSTEM	Not a prosthesis. Adding a consumable item whether cost neutral or not is not consistent to a prostheses. No evidence of a Health Technology Assessment (HTA).	Reject
N001699 – DAC 5ML	Not a prosthesis. "It may only last one day." "Both clinicians agreed that the information submitted by the applicant had not been sufficient to inform assessment of the comparative clinical effectiveness of the device." We'd be interested in an HTA to determine if it should be funded by other means.	Reject
SURGICAL GUIDES AND ANATOMICAL MODEL	Not a prosthesis. "These devices are not surgically implanted." An expedited review is warranted and should take about five minutes to determine these are not prostheses. We'd be interested in an HTA to determine if it should be funded by other means. Software-based diagnostic imaging technology are not prostheses nor are the essential to the implantation of the device. They are software, and are growing at over 100% YoY. The plates themselves are attracting a premium (which may or may not be valid but the software should not be charged as an additive cost).	Reject Remove existing items
MEDICATION INFUSION DEVICES	"Infusion pumps that deliver medication to patients are not surgically implanted, are not integral to implanting a prosthesis and are not essential to the functioning of a prostheses. Thus, they do not satisfy the criteria for listing on Part A of the Prostheses List." Existing items should be removed in the February 2020 listing. That should give time to address any contractual issues. It's worth noting that some of the more expensive devices have "full colour screens" – these are not implanted, and indeed can be reused for multiple patients. They are not even consumables and have no place on the PL.	Reject Remove existing items
N001720 – GrowIT	Not a prosthesis. It's a pharmaceutical agent.	Reject

	The product fails the criteria and is different to the items it quotes as comparators. It requires a detailed HTA before any consideration, this data will not be readily available to determine if it should be funded by other means.	
N001619 N001632 – StabiliT	Unlikely to be a prosthesis. Not enough information on anything really. No evidence for an operation that was removed.	Reject
N001515	While noting that this item has had the revision suffix rejected, Braun are still making significant unwarranted income from a range of PL items that have the revision suffix but are being used in primary procedures. It is now a year since PHA wrote to the Department on this issue.	Agree with CAG
N001517-2 N001517-3 N001517-4	PHA is concerned that there is no evidence that these items have been used in humans, but note the CAG advice on listing.	Agree with CAG
N001522 and N001523	Agree	Agree with Dept
N001547-1	This is an infusion pump, see above	Reject
N001547-2	This is an infusion pump, see above	Reject
N001549	OverStitch Sx Endoscopic Suturing System List at same level as existing device, noting MSAC review in place.	Support
N001552 and N001458	These are gels – not a prostheses. They will be captured by the general and misc review, so we can either reject now or should defer while we await the results of the review.	Reject or Defer
N001569-1 N001569-2	cervical plates	Agree with CAG
N001573 HEMOPATCH SEALING HAEMOSTAT	This is not a prostheses. Could the department please advise what usage is anticipated? Has this item been in use previously (and covered by DRGs)? The papers suggest that it will be used in neurosurgery – what MBS items is it suggested to be restricted to? They will be captured by the general and misc review, so we can either reject now or should defer while we await the results of the review.	Reject or Defer
N001577-2 N001584-2	Screws	Agree with CAG

N001600	Clavical plating system. Agree on all points	Agree with CAG
N001601-3	Screws	Agree with CAG
N001609	Sacral Nerve Stimulation Accessories (a needle) It's not clear that the needle is left in the patient – is it a prosthesis? Need clear advice that the needle is a prosthesis and not a consumable. May be considered essential for implantation, agree with the revised price point for an each.	Support Dept recommended price for 'an each' code
N001615, N001616, N001622	Ablation Catheter The CAG is right not to accept as evidence a report of a clinical trial not published in internationally recognised journals. They should come back with a higher quality of evidence. CAG and Department should review the methodology and data, and seek additional utilisation information from other markets.	Defer seeking wider data
N001624 Comfort drain	This is not a prosthesis. It's a drain. Given lack of clarity on function and that it sits within General and Miscellaneous, approving not valid.	Reject or defer
N001627-1	Nail. Agree with CAG to support a new grouping and the proposed price.	Agree with CAG
N001641-9	Axonics Foramen Needles It's not clear that the needle is left in the patient – is it a prosthesis? Need clear advice that the needle is a prosthesis and not a consumable. Support the pricing of a per unit basis	Support proposed single unit Price point.
N001674 N001675	Plates. Agree with department and CAG, list without locking.	Agree with Dept
N001685 HEMOPATCH SEALING HAEMOSTAT	This is not a prosthesis. Could the department please advise what usage is anticipated? Has this item been in use previously (and covered by DRGs)? The papers suggest that it will be used in neurosurgery – what MBS items is it suggested to be restricted to? They will be captured by the general and misc review, so we can either reject now or should defer while we await the results of the review. Need clear understanding does this product substitute the other products or is an add to them in the same procedure. Well and good to say it has two properties, but will it replace the other products.	Reject or Defer Subject to economic model understanding given new group
N001688 MyCareLink Heart Mobile Application	This is not a prosthesis, it's an app.	Reject
N001703 uretheral stent	Support HTA approach (noting that a short stay device is not in the spirit of the PL).	Defer

N001709	Plates Support CAG advice	Agree with CAG
N001714	Screw Concur with CAG advice	Agree with CAG
N001716-2	Screw Concur with CAG advice	Agree with CAG
N001717 Urethral drug coated balloon catheter	Does not appear to be a prosthesis and should not be listed. We'd be interested in an HTA to determine if it should be funded by other means (subject to TGA approval etc). Insufficient data the trial is set to end 2023. Effectiveness data should be generated from trial	Defer extended for clinical and cost effectiveness data

Agenda item 6.2

Agree to the recommendations with the following exceptions:

Item	Comment	Rec
N001514 - INTRAOCULAR FLUIDS	This is a consumable, not a prosthesis. As the clinician noted "methylcellulose viscoelastics are routinely in use." They are paid through DRGs – placing them on the PL is inflationary with no consumer benefit. Review required of this group, for appropriateness for inclusion on PL, covered under consumable agreements	Approve based on comparator not appropriateness for PL
N001641-x	External neurostimulator and accessories Are these items prosthesis? Are they being implanted in the patient?	Approve based on comparator not appropriateness for PL
N001646	Synthetic Bioresorbable Mesh This is not a prosthesis – it is absorbable This will be captured by the general and misc review, so we can either reject now or should defer while we await the results of the review.	Reject or defer
N001647	Synthesised biologic, resorbable Hernia mesh This is not a prosthesis – it is absorbable This will be captured by the general and misc review, so we can either reject now or should defer while we await the results of the review.	Reject or defer
N001648	Fully resorbable biologic hernia mesh with added barrier to assist adhesion prevention This is not a prosthesis – it is absorbable This will be captured by the general and misc review, so we can either reject now or should defer while we await the results of the review.	Reject or defer
N001655	Meniscal suture anchor Since the sponsor may had misled the PLAC on DE649, we need to take a good look at this one. Could the department please advise what usage is anticipated? Has this item been in use previously (and covered by DRGs)? What MBS items is it suggested to be restricted to?	Defer, seek advice
N001656	TightRope implant pre-loaded with FiberTag suture Since the sponsor may had misled the PLAC on DE649, we need to take a good look at this one. Could the department please advise what usage is anticipated? Has this item been in use previously (and covered by DRGs)? What MBS items is it suggested to be restricted to?	Defer, seek advice

Agenda item 6.4

Item	Comment	Rec
N001641-1 Axonics Neurostimulator	As per dept advice, await HTA	Defer, seek advice
N001641-3 Axonics Charging System	This is not a prosthesis. As per dept advice, await HTA	Reject
N001660-1 dental bridge	This is not a prosthesis. As per the clinical advice "the device is clearly a dental product and has nothing to do with surgery."	Reject as per dept advice

Agenda item 6.5 amendments

- Note that many of the items are not prostheses, and will be subject to the general and miscellaneous review.

Recommendations accepted, with the following exceptions:

Item	Comment	Rec
A023851 mesh	The packaging has changed from a pack of five to a single unit – meaning funds will be paying five times as much for the same amount of product. (Note not a prosthesis.)	Reject
A023852 mesh	The packaging has changed from a pack of five to a single unit – meaning funds will be paying five times as much for the same amount of product. (Note not a prosthesis.)	Reject

Agenda item 6.6 amendments not supported

Nil comment

6.7 higher benefits

Recommendations accepted, with the following exceptions:

Item	Comment	Rec
A023562 sealant	This will be captured by the general and misc review, so should defer while we await the results of the review.	Defer
A023572 mesh	This will be captured by the general and misc review, so should defer commissioning the HTA while we await the results of the review.	Defer
A023659 stapler	This will be captured by the general and misc review, so should defer while we await the results of the review.	Defer
A023750 shoulder cup	CAG advise to reject	Reject
A023767 screw	CAG advise to reject	Reject
A023803 screw	CAG advise to reject	Reject
A023816 plates	CAG advise to reject	Reject
A023818 plate	CAG advise to reject	Reject
A023819 plate	CAG advise to reject	Reject
A023836 mesh	The Department recommends that the application should be referred for an HTA to inform the appropriate benefit and patient population.	Defer

6.8.1 Reviewed item - MIS IMPLANTS APPLICATIONS N001416 AND N001417

These applications were described as a 'rort' by the clinical adviser, unbundling items in order to gain a higher benefit. There is nothing in the response that suggests that the application has addressed this issue. Reject. A review of the listings and benefits of dental implants, cover screws/healing caps and abutments is required.

6.8.2 Reviewed items - VASCULAR EMBOLISATION BALLOONS – APPLICATIONS TO RE-GROUP

These items are not prostheses. They should be rejected. The listing of vascular embolisation balloons should be included on the list of potential reviews.

7. Abbreviated pathway

Private Healthcare Australia is opposed to the abbreviated pathway. It is not reasonable for the payers to have no opportunity to review listings. We are happy to continue working with the department on options for an abbreviated pathway with an opportunity to review before finalisation of advice to the Minister.

8A. Reform activities

Combined QIG and BSR Meeting report

Private Healthcare Australia does not agree that the Prostheses List should include non-implantable devices, while noting the meeting's participants not responsible for funding prostheses "generally supported expansion of the list to include non-implantable devices in some circumstances"