CATHOLIC HEALTH
Australia

2 June 2017
Prostheses Reform

Draft Proposed Approach for Targeted Prostheses Reviews

Catholic Health Australia (CHA) welcomes the Minister's press release advising of the Prostheses Listing Advisory Committee's (PLAC), "Proposed Approach for Targeted Prostheses Reviews". CHA is also pleased to note that a targeted review of prostheses was also a recommendation from the Senate Inquiry into Community Affairs (Price regulations associated with the Prostheses List framework) report (11 May 2017).

The suggested framework outlined in the draft proposal, while scant on specific detail, appears to address a number of recommendations including improved:

- coordination between government bodies and stakeholders;
- transparency in the review process;
- device efficacy and value for consumers; and
- the need for more robust data collections to align price with efficacy and health outcomes for consumers

While acknowledging that the intent of the draft proposal was to outline an indicative approach, CHA would like to highlight the following considerations for inclusion into any framework going forward, with particular emphasis upon utilising an evidence-based, and rigorous review process – without pricing deliberations compromising:

1. The quality of products provided in the Australian market;
2. The role of Clinical Advisory Groups
3. Health outcomes
4. Consumer choice and access to evidence supported prostheses

Pricing and product quality:

If benefit setting for new/equivalent or novel products are to be reconsidered under a revised framework, CHA recommends careful analysis of products being promoted at a significant price reduction. Any compromise of product quality and/or clinical effectiveness needs to be avoided. Having items rejected or removed from the Prostheses List on the grounds of safety or efficacy concerns (as appears to have happened in the past) whilst those items still remain on the Australian Register of Therapeutic Goods and therefore accessible in the public system, leaves open the question of a two tiered safety and quality system. CHA supports greater integration of the roles of the Clinical Advisory Group (CAG), (TGA) and MSAC to ensure pricing reflects the right imperatives.

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Role of the Clinical Advisory Group (CAG):

CHA acknowledges and highly regards the unique level of expertise brought to the table by the participating clinicians of the CAG. CHA recommends improving the criteria within which the Clinical Advisory Group (CAG) operate including ensuring that criteria for the review of the prostheses grouping structures is fit for purpose. The CAG Terms of Reference should provide a safeguard to encourage a more independent and robust assessment of products. The role of the CAG should include principles for medical assessment. Additionally, to ensure transparency, each device recommended by a member of CAG should be 'signed off' to confirm that in reaching a determination there was 'no professional conflict of interest'.

CHA also supports that recommendations by the Panel of Clinical Experts should also be made more transparent and the PLAC must ensure that it has a minimum number (more than one) of experts with agreed positions when making recommendations to the PLAC.

Clinical Outcome Data:

The Prostheses List (PL) was designed to provide benefits for medical devices that are clinically and cost effective, but we currently lack the oversight and assessment bodies to systematically review this evidence. Post market surveillance in Australia is largely lacking. With the exception of the Australian Orthopaedic Association National Joint Replacement Registry, there are limited outcome driven reviews to compare the clinical effectiveness of prostheses. Establishing and ensuring greater industry capture of data across a number of clinical specialties area would greatly assist independent clinical review. However, even with immediate introduction, a 'data lag' would prevent robust analysis for informing device efficacy and/or targeting of any potential products for removal in the immediate 2 to 5 year period. The majority of prostheses spend in this country is on the categories of joint replacements, cardiac, spinal and ophthalmology. CHA supports that prostheses registries should be fast tracked for cardiac , spinal and ophthalmology items.

Where outcomes are better understood, devices that are found to be of greater clinically benefit/survival, items should be listed in such a way that they are easily identifiable on the PL to assist clinicians and hospitals with selection and procurement.

Other considerations:

Prostheses are not generic:

Unlike pharma where the change from one drug to another bioequivalent or biosimilar can be undertaken with relative confidence that both drugs are the same, changing prostheses preferences is more complicated. Prostheses implantation relies heavily on the skill and experience of the surgeon implanting the device. Many surgeons train using a particular type of prostheses. There is a strong evidence based correlation between good clinical outcomes and high volumes and standardisation of procedures. Quite simply, surgeons "get good at" carrying out procedures using particular devices. Unlike changing a drug to a bioequivalent, changing prostheses must take into account the human factors of changing the implantation procedure to accommodate a different prostheses and its application kit. It is not a case of a simple swap.

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Rationalisation of the PL:

While not specifically indicated as a consideration 'in scope' for targeted reform, coincidental findings under the review framework may allow for assessment of devices by volume utilisation. Devices with low or negligible utilisation over the last 12 month period may be considered suitable for removal (in consultation with the supplier); or where a component may be required for surgical revision procedures (noting that clinical evidence supports that when replacing one component of set of prostheses, it should be from the same set) in the future, moved to a 'spare parts' listing or 'Part D'. Devices that have no utilisation and could not otherwise be classified as 'components' of a set or likely to be required in a surgical revision could be de-listed.

'Floor' pricing and 25% market share:

The existing method for setting a benefit level on the PL required a product in the category to have a 25% market share in order to set the benefit group pricing. This guideline was instigated to ensure that the consumers had access to no-gap PL items. Recommendations that were presented during the Senate Inquiry suggest a new entrant into a subcategory that offers a lower price could trigger a review of current benefits. While this would encourage a more competitive market for devices, there should be mechanisms in place to ensure that consumers continue to have access to high quality items with no gap. Re-pricing a whole category on the basis of a cheap new item could leave the consumer paying gaps in the events that clinicians to not change their practice to incorporate the new item. There would need to be confidence that the items in the sub-categories were the prostheses equivalent of the pharma's bioequivalence. To date the categorisation of the items on the PL has not be that specific.

The role of hospitals:

CHA supports the importance of including into the scope of any review the consideration of market value, indirect costs involved in supplying the device and value to patients. Hospitals should be encouraged to participate in costing studies that improve transparency and contribute to better patient outcomes. Improved methodology in the allocation of prostheses costs in studies would assist greater confidence in the apportionment of costs. Additionally, the difficulty with costing studies undertaken across the private sector is that there are no consistent cost accounting frameworks between hospitals/hospitals groups. Incentives that encourage hospitals to disclose information could assist in the effort to improve transparency. Any new review should not rely upon the public sector cost study outputs which are largely driven by modelled cost buckets and have no sensitivity to the actual type of prostheses utilised.

Health funds can assist in the comparative analysis through the provision of industry-related evidence where variations in public and private costs are greatest. PLAC will be able to review these categories in detail and information gathered from hospitals and suppliers could elucidate some of the differences in price disparity that may not be fully captured in the public sector. Where true price differentials exist, CHA supports a reform process that includes honest and open dialogue amongst stakeholders and the 'calling out' of misinformation, to ensure a constructive transformation and greater stewardship of the Australian health care dollar.