Submission for Senate Inquiry:

Price Regulation associated with the Prostheses List Framework

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1. Executive Summary

- The **current laws and regulations** in the field of Private Health Insurance are **ambiguous**. As a consequence, the approach adopted by health funds in inconsistent across the industry. We recommend this ambiguity be resolved. One such example is the definition of 'hospital treatment' and its **effect on the coverage of replacement sound processor technology**.
- The cost to the Sponsor of providing the **necessary support and service** to the hospital and patient shall be defined and **reflected in the purchase and reimbursement** of prostheses. The scope of necessary service and support may differ by product category and service delivery models.
- The Terms of Reference of the reconstituted Prostheses List Advisory Committee's (PLAC's) and its sub-committees are appropriate. The role of the Health Economic Sub-Committee **(HESC) should be expanded** to provide advice on the cost effectiveness of devices **throughout the product's listing lifecycle**.
- In Australia the **price/ benefit of cochlear implant systems** (within the ENT product category) are consistent between private and public health settings and are typically **less than the prices cited in international reference prices** from health care systems in developed economies.
- The **same level** of professional training, patient management, product management and **support is provided in the Australian public hospital sector and private health** care system. Different models of service and support and payment thereof may prevail across international jurisdictions. Comparisons across jurisdiction should consider these factors.
- A **revision of the definition of 'prostheses'** and the **introduction of a benefit re-evaluation process** as part of the Prostheses List framework is recommended as way of ensuring the most cost effective interventions are provided and appropriate reimbursement benefits are maintained.
- The use of domestic and international **reference pricing of prostheses should continue to be utilised as an input** into benefit setting and amendment processes. However, other criteria for the setting and evaluation of benefits need to be available for new, particularly Australian, innovations, which may not yet have an established domestic or international price nor utilisation data.
- Cochlear raises concern about the **lack of clarity regarding the transition of Australian Hearing (AH) clients to the National Disability Insurance Scheme (NDIS)**. This is resulting in confusion and uncertainty individuals, providers and suppliers. No solution has been defined for the ongoing support of some of Australia's most severely hearing impaired and financially vulnerable - those AH clients > 65 years.
- Until NDIS fully rolled out, we will not know what coverage will be available for Australians with a permanent severe to profound hearing impaired. **PHI coverage** of replacement sound processor technology must **continue to support timely access for those insured.**

2. About Cochlear

Cochlear is the global leader in implantable hearing solutions. Cochlear is one of Australia's major medical device companies, designing, manufacturing and exporting implantable hearing devices. The company has a dedicated global team of approximately 3,000 people who deliver the gift of sound to the hearing impaired in over 100 countries. Our mission is to connect people, young and old, to a world of sound by offering life enhancing hearing solutions. Cochlear's promise of "Hear now. And always" embodies the company's commitment to providing its customers with the best possible hearing performance today and for the rest of their lives. For over 30 years Cochlear has helped over 450,000 people to either hear for the first time, or reconnect to the sounds of their families, friends, workplaces and communities.

3. Implantable hearing systems

Cochlear currently offers two categories of implantable hearing systems in Australia. Both are available in the Private and Public health system.

3.1. The Cochlear™ Implant System

The Nucleus® brand cochlear implant systems consists of a surgically placed cochlear implant and an externally worn sound processor. The sound processor is fit by an audiologist and is programmed to suit the individual patient's hearing fingerprint. The system requires a lifetime of professional care and follow-up.

Figure 1. The Components of the Cochlear™ Nucleus® 6 Cochlear Implant System

3.2. The Implantable Bone Conduction Hearing System

The Baha® brand of implantable bone conduction hearing systems consist of surgically placed titanium fixtures and an externally worn sound processor. Like the cochlear implant system, the sound processor is typically fit by an audiologist and the patient requires a lifetime of professional care and follow-up.

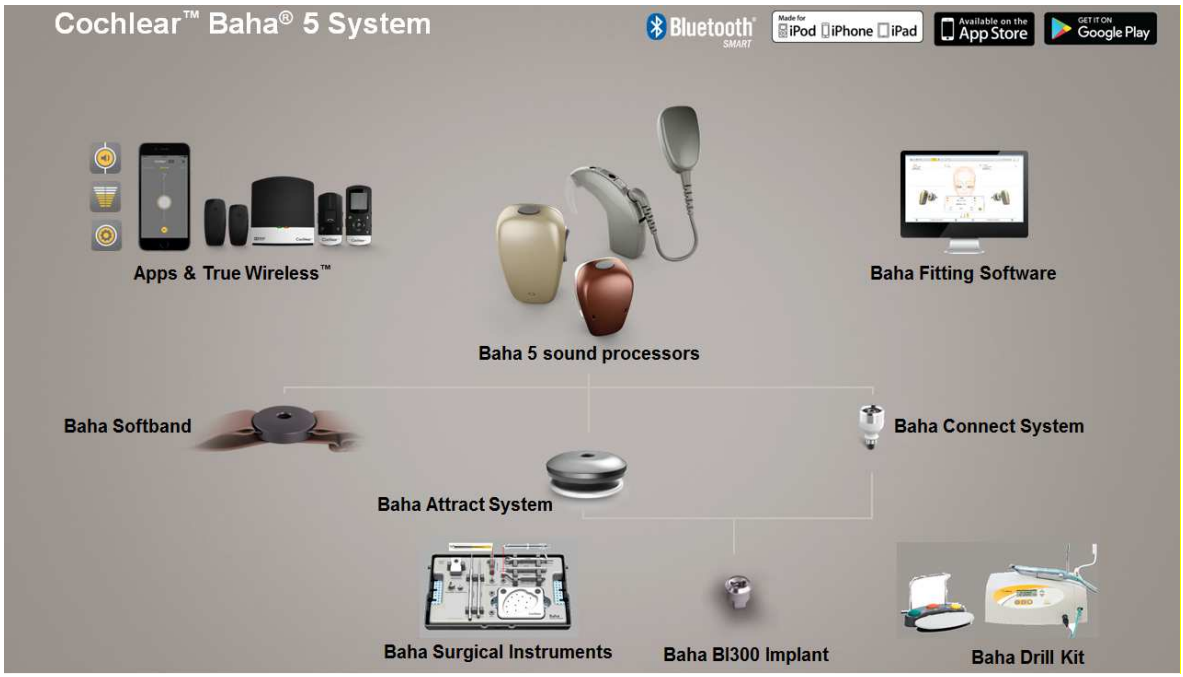

Figure 2. The Components of the Cochlear™ Baha® 5 implantable bone conduction system

As illustrated in Figures 1 and 2, the fitting and management of Cochlear's Implantable Hearing Systems require a suite of supporting components. These include: Surgical tools and drill kits as well as proprietary hardware and software are required for the programming of the devices. Such costs are, and should continue to be, reflected in the benefit level paid for these devices.

4. Principles

Cochlear supports the principles to be considered when reviewing the key mechanisms for prostheses benefits as set forth in the AusBiotech/AusMedtech response to the Reform of Prostheses Benefits – Research, December 2016.

5. Terms of Reference

This submission responds to Terms of Reference: a, b, c, d, e, f, g, and j.

5.1. a) The operation of relevant legislative and regulatory instruments

The legal framework of the *Private Health Insurance Act, 2007*[1] (**the Act**) is designed to encourage more Australians to have private health insurance. However the value proposition of private health insurance may be challenged by possible limitations and apparent ambiguities between provisions of the Act, *Private Health Insurance Rules*[2] (**the Rules**), and the *Private Health Insurance Guidelines*[3] (**the Guidelines**).

Cochlear's implantable hearing systems fulfil the Eligibility for Listing criteria defined in Section 72-1 (2) of the Act and therefore are included on Part A of the Prostheses List. However the interpretation of hospital treatment in section 121 of the Act adopted by health funds is inconsistent across the industry. This is confusing for the insured individual and the treating clinicians who are not assured of coverage for the replaceable external part of their hearing system (sound processor).

We recommend that this ambiguity be resolved such the provision of audiological services (MBS numbers 11300, 82300) necessary for the fitting and ongoing management of implantable hearing systems are included under the scope of hospital treatment.

This will mean that Cochlear Implant and bone conduction implanted insured members will have certainty that the necessary post implantation service and support (Refer Section 5.2, ToR b), in particular the provision of replacement sound processors, will be covered by relevant insurance products.

The current laws and regulations in the field of Private Health Insurance are ambiguous. As a consequence, the approach adopted by health funds in inconsistent across the industry. We recommend this ambiguity be resolved. One such example is the definition of hospital treatment and its **effect on the coverage of replacement sound processor technology**.

5.2. b) Opportunities for creating a more competitive basis for the purchase and reimbursement of prostheses;

The purchase and reimbursement of active implantable devices, such as Cochlear's implantable hearing systems portfolio must consider more than just the purchase of a device used in a surgical episode. In line with Australia's approach to patient centred models of care, hospitals and substitute hospital treatment centres require Sponsors to provide service support to the hospital, troubleshooting services and long term patient management. The costs or providing the Service and Support, necessary optimal patient outcomes are considered in the purchase and reimbursement of cochlear implantation in Australia.

The scope of Service and Support that may be required[4]:

- Provide troubleshooting services and long term patient management.
    - Long term device Mapping
    - Device trouble shooting and repairs
    - Processor upgrades
    - Provision of loan processors while the patients is being repaired or replaced
    - Liaising with Australian Hearing and the National Disability Insurance Scheme for funding of processor upgrades and the provision of clinic support documentation.
    - Sale of sound processor accessories
- Develop implant outreach services and other service partnerships to increase access to services and reduce travel time for patients.
- Strengthen current partnerships and develop future partnerships in research and education.
- Deliver the quantity of the implant systems at the level necessary for the Hospital's requirements for public and private patients.
- Deliver hands on education and training packages to ensure clinical audiology staff develop the specialist skills required to operate the information technology systems and software packages.
- Provide regular updates and training to the Cochlear Implant clinic staff on any product changes, new devices or new accessories so that their skills and knowledge remain current.
- Deliver education and product training packages to ensure surgeons develop specialist knowledge and can refine surgical procedures.
- Provide theatre staff with required training on surgical instruments in order to adequately prepare and support cochlear implant surgical sessions.
- Provide instruments required for surgical procedures.
- Provide the clinic with sufficient free back up implants to support difficult theatre cases. The hospital will only be billed for the device that is implanted in the patient.
- The hospital will be provided free of charge, all hardware that is required to undertake device programing, including cables, programming interfaces/units etc.
- The provider will provide free of charge, spare functioning sound processors which will be available to the clinic to enable troubleshooting as well as free demo kits to be used in the clinic for patient counselling.
- Ensure that implants and processors are received within agreed timelines to facilitate surgical sessions and clinic functions. This may require short turnaround times for urgent surgical cases
    - Provide implant systems to the Hospital within 5 working days of the order being placed.
    - Provide cochlear implant to the hospital within 24 hours of the order being placed for urgent surgical cases.

- Provide implant ordering systems that are user friendly, easy and quick to use and can provide tracking of device provision progress. Ordering systems will ideally be able to interface with the hospitals finance/ procurement systems.

The cost to the Sponsor of providing the necessary support and service to the hospital and patient shall be defined and reflected in the purchase and reimbursement of prostheses. The scope of necessary service and support may differ by product category and service delivery models.

5.3. c) The role and function of the Prostheses List Advisory Committee and its subcommittees;

As per the reconstituted Prostheses List Advisory Committee's (PLAC's) Terms of Reference[5], their role is to make recommendations and provide advice to enable the Minister to exercise his or her powers under the Private Health Insurance Act 2007. This includes:

- making recommendations to the Minister on whether applications to list medical devices should be granted or not and if any conditions of listing are appropriate;
- advising the Minister about the benefits for medical devices to be listed on the Prostheses List;
- advising the Minister on requests to amend current listings on the Prostheses List; and
- reviewing the listing and/or benefits of listed medical devices as appropriate and make recommendations to the Minister

These Terms of Reference are appropriate, noting that the definition of processes that provide a structured, transparent approach the ongoing listing and benefit re-evaluation need to be established.

The PLAC's recommendations and advice are to be based on assessment of comparative clinical effectiveness and cost effectiveness of medical devices using the best available evidence. Contrary to IWG's recommendations[6], the PLAC should not be providing advice to the Minister about the comparative safety of prostheses. This should be, and remain the responsibility of the Therapeutic Goods Administration (TGA). However, the Panel of Clinical Experts[7], and Clinical Advisory Groups[8] should continue to raise any concerns regarding the intrinsic safety and efficacy of any device which should be communicated and evaluated by the TGA. This should not replace the required timely reporting of any device related concerns to Sponsors as part of required post market surveillance responsibilities.

Similarly, PLAC itself is unlikely to best placed to establish a routine process of post-marketing monitoring and reviews of prostheses. Establishment of necessary post market registries should remain the responsibility of the TGA. Output from such registries should be considered as input into the PLAC's listing and benefit re-evaluation processes.

This is in line with the current PLAC Terms of Reference which state that "The PLAC should liaise with the MSAC, the TGA and PBAC to develop assessment processes that maximise the use of the clinical and technical expertise of each body and reduce duplication of assessment."

The use of Clinical Advisory Groups and Panel of Clinical Experts should continue to provide advice on the clinical effectiveness of devices at the time of listing. This could be expanded to assessment of clinical effectiveness for future Listing and benefit re-evaluation processes.

Currently, the HESC assesses the sponsor's proposed benefit for a new product to be listed in a new grouping on the Prostheses List and provides advice to PLAC on the validity of the proposed benefit. The role of the Health Economic Sub-Committee (HESC) should be expanded to provide advice on the cost effectiveness of devices throughout the product's listing lifecycle. This could also include the evaluation of cost effective interventions that utilise medical devices that fall outside the current definition of "prostheses".

The Terms of Reference of the reconstituted Prostheses List Advisory Committee's (PLAC's) and its sub-committees are appropriate. The role of the Health Economic Sub-Committee (HESC) should be expanded to provide advice on the cost effectiveness of devices throughout the product's listing lifecycle.

5.4. d) The cost of medical devices and prostheses for privately insured patients versus public hospital patients and patients in other countries

There are multiple factors that should be considered when comparing and contrasting the cost of medical devices and prostheses across domestic and international healthcare systems.

5.4.1 Health care systems and structure

There is a wide variety of healthcare systems around the world, delivering services to their target populations. Many developed economies have implemented national healthcare systems proving universal coverage to their populations. These may take a number of forms:

- A single-payer national health insurance system e.g. Taiwan, Japan, UK, Canada
- A multi-payer universal health insurance system e.g. Germany, France
- Hybrid single payer/ private health insurance systems e.g. Australia

In contrast, the US does not have a uniform health system and until recently has not mandated healthcare coverage for all citizens.

The structural differences and objectives of these diverse healthcare systems must be carefully considered when evaluating international reference pricing comparisons. Hence the applicability of international reference pricing in Australia's private hospital sector is limited.

Unlike some categories of product, in Australia the price/ benefit of cochlear implant systems (within the ENT product category) are typically less than the prices cited in international reference prices from health care systems in developed economies.

5.4.2 Funding and Procurement Practices

The structure of a health care system and the associated legislative framework will also affect the funding, reimbursement and procurement practices.

In the **Australian Public Hospital sector**, the procurement of prostheses is driven by Activity Based Funding and some block funding. There is a strong incentive for State Governments/ Hospitals to purchase the lowest cost device. Public tenders are frequently employed to purchase large volumes of devices for a given budget over a specified period of time.

Public tenders are appropriate for the procurement of some categories of devices, particularly those in which there is high competition. A consequence of centralised purchasing via tender is that it will limit the choice of prostheses available. This is contrary to the value proposition of private health insurance.

For lower volume interventions, such as Cochlear's implantable hearing systems, the use of tenders even in the public hospitals is not common. Cochlear transacts on individual orders per patient.

The **Australian Private Hospital Sector** has different financial constraints and incentives. As such the purchasing systems and practices are different. Surgeons choose which device they would like to use for their patient, from the range of devices included on the Prostheses List. These are paid for by the private health insurance funds. As in the public hospital setting, cochlear transacts on individual orders per patient for its products.

Timely access to the most clinically appropriate device for the individual patient's condition, is a key element of the value proposition of private health insurance and must be maintained. Cochlear supports the continued use of a Prostheses List.

The purchasing processes for Cochlear's implantable hearing systems is the same in Australia's public and private hospital sectors. As each device is ordered per patient per episode of care, in both settings, this does not affect the price/ benefit of the device.

5.4.3 Professional Training and Support

Training and support for optimal use of medical technology is required. The level of this support will be dependent on the type of device, its innovative content and the stage of its lifecycle.

Professional Training – product introduction:

- For completely new technologies, where no predicate device exists, a detailed training program will be required for implanting surgeons, operating theatre staff and any relevant allied health care providers.
- Most frequently Cochlear introduces new products that incorporate incremental innovations on the previous generation of products. For the surgically placed portion of the implantable hearing system, training on these improvements are largely provided by trained company representative in the operating theatre.
- Training for audiologists is frequently required to support the introduction of a new model sound processor, as frequently this requires the implementation of new proprietary software and hardware required for the programming of this device.

Professional Support – product support:

- Following the initial introduction of a new device, a surgeon may request that a trained company representative be present in the operating theatre. This would be typical if: the surgeon is new to the procedure, there is a difficult case planned, the operating theatre staff are not familiar with the device/ procedure, decisions about the use of devices in the procedure need to be made within the operating room. For these reasons surgical support is required for < 20% of cases for cochlear implantation but for approximately 80% of cases for the implantable bone conduction hearing system. These estimated cost of this support is AUD 0.48M per year.
- Audiologists play a key role in the fitting and support of implantable hearing systems. These audiologists may be employed by the hospital in the public sector but will typically be operating in a private audiology facility, associated with the individual surgeon, in the private sector.
- Audiologists may request technical support from our Clinical Specialists post implantation if: they have are building their capability and experience with the programming and management of the cochlear implants or Baha, for difficult cases and if there are concerns about the functioning of the hearing device. These estimated cost of this support is AUD 1.5M per year.

The same level of professional training and support is provided to surgeons and audiologists whether in the Australian public hospital sector or private health care system. Different levels of service and support and payment thereof may prevail across international jurisdictions.

5.4.4 Patient Management and Support

As Cochlear's implantable hearing systems are used by the patient for the rest of their life, direct service and support for these patients is required. This may take the form of: 24/7 troubleshooting, sale of spare parts and accessories, management of service repairs of sound processors and is delivered through on-line and off-line services. The estimated cost of this support is AUD 0.96M per year.

The same level of patient management and support is provided to all patients. There is no difference between patients implanted in the Australian public hospital or private hospital sector. The provision of patient support may be delivered through different service models in international jurisdictions.

5.4.5 Product Management and Support

To date, Cochlear's devices have not been placed on consignment in either the public or private sectors. Product is supplied per surgery / episode of care across Australia from our Sydney headquarters. In addition to the devices ordered, the following items are also shipped per surgery:

- Cochlear Implants: a second cochlear implant is shipped, as a back-up device, for every surgery. This is returned to Cochlear if it is not required. Cochlear bears the freight costs and insurance liability for these back-up devices. This has an estimated cost of AUD 0.4M per year.
- For our Baha® implantable bone conduction hearing system, the surgical drill kit and associated equipment must also be prepared, repacked, and shipped for every surgery. Cochlear bears the entire cost, which is estimated to cost AUD 0.28M per year.

Costs associated with the management and support of devices included on the Prostheses List should be factored into the benefits set.

The product management and support processes for Cochlear's implantable hearing systems are the same in the Australian public hospital or private hospital sector. Different processes may exist in international jurisdictions.

5.5. e) The impact the current Prostheses List Framework has on the affordability of private health insurance in Australia

Over the past 5 years Private Health expenditure on Prostheses has represented between 13% – 14% of the expenditure on Hospital Treatments (Refer Table 1). During this time the total amount paid to insured persons for prostheses items has increased, largely due to the higher utilisation rates of prostheses rather on ever increasing benefits paid per prostheses group.

Notably, without a structured price re-evaluation process as part of the Prostheses List Framework, there have not been significant increases or decreases in benefits paid per prostheses group. The benefits paid for Generation 4 cochlear implants ($13,570) and sound/ speech processors ($11,500) has not changed since 2005 (Refer Table 2).

Unlike Private Health Insurance premiums, prostheses benefits are not indexed for Consumer Price Index (CPI) nor any other relevant cost drivers.

Ta**ble 1.** Reported expenditure on Hospital Treatments and Prostheses items

Expenditure	**2011/2012**	**2012/2013**	**2013/2014**	**2014/2015**	**2015/2016**
Hospital Treatments (HT) $ billion	10.6	11.28	12.4	12.85	13.72
Prostheses Items (P) $ billion	1.48	1.5	1.7	1.8	1.967
% P/ HT	**13.9**	**13.4**	**13.7**	**14**	**14.3**

Source: PHIAC Quarterly Reports

Table 2. ENT Grouping Scheme for Cochlear Implants

Groupings	**Benefits**
02 - Ear, Nose & Throat	
02.01 - EAR	
02.01.01 - Cochlear Implants	
	$ 13,570
02.01.02 - Speech Processors	
02.01.02.01 - Initial	
	$11,500

Source: Grouping Schemes for ENT category of product, including suffix definitions and benefits

The introduction of a Benefit re-evaluation process for ongoing listing of devices should be introduced and is discussed under ToR g. in Section 5.7.3 of this submission.

At a more macro level, due consideration should be given to the definition of prostheses. There are some interventions that are more cost effective than those requiring the use of items currently eligible for inclusion on the Prostheses List. Due consideration should be given to ensuring privately insured patients have timely access to the most clinically suitable, cost effective intervention.

A revision of the definition of 'prostheses' and introduction of a benefit re-evaluation process as part of the Prostheses List framework is recommended as way of ensuring the most cost effective interventions are provided and appropriate reimbursement benefits are maintained.

5.6. f) The benefits of reforming the reference pricing system with Australian and international benchmarks

Currently Sponsors are required to provide any Australian or International Price and Utilisation data under the "Product Utilisation" section of the Application Forms to List or Amend the listing a Prostheses.

The use of domestic and international reference pricing of prostheses should continue to be utilised as an input into benefit setting and amendment processes. However, other criteria for the setting and evaluation of benefits need to be available for new, particularly Australian, innovations, which may not yet have an established domestic or international price nor utilisation data. This may include cost accounting methodologies and/ or economic evaluations.

As presented in Cochlear Limited's submission to in Relation to Reform of Prostheses Benefits, Research - Longer Term Benefit Setting Framework, the following recommendations were made for use of reference pricing.

5.6.1 Domestic reference pricing

This may be relevant if the Prostheses is already being used in the Australian Market, following TGA approval, and/or if the Australian healthcare system has been used for the clinical and health economic evaluation of the intervention.

- Median of awarded tender prices adopted by public hospitals, or median price sold to public hospital items not procured through public tenders.
- The cost of prostheses defined in relevant clinical evidence such as that used to establish cost effectiveness.
- Adjust by some factor/ algorithm, which should account for:
    - Innovation that improves patient outcomes, clinical practice and the long term cost of care.
    - Differences in procurement practices, funding systems, product management and support.
    - The level of training and professional support required for safe and effective use. This may be higher in the first year or two of listing a new technology.

- Provision of patient management and support required by the Sponsor over the life of the device and/or the life of the patient.

5.6.2 International Reference Pricing

International reference pricing (IRP) may be used as an input into the benefit setting process for new technologies that have not yet been launched in Australia. However, due to the complexity of adjusting for differences in health care systems across multiple jurisdictions, there may be significant challenges in defining algorithms to adjust median IRPs to inform benefit levels of prostheses in the Australian Private Health Insurance environment. Refer to EFPIA, 2014[9] for explanation.

Due consideration must be given to:

- How this reference pricing data is adjusted for differences between the relevant healthcare systems and structures, as outlined under ToR d above.
- Whether other sources of domestic and /or international reference pricing are used by the HESC and the validity of those sources and their interpretation.
- Ensure industry will have an opportunity to verify the data being used and /or respond to possible outcomes resulting from this reference data before any subsequent decisions are finalised.
- Necessary provisions for inclusion of innovative Australian healthcare-solutions, such as those resulting National Science and Innovation Agenda Biomedical Translation Fund, on the Prostheses List.

5.7. g) The benefits of any other pricing mechanism arrangements, including but not limited to those adopted by the Pharmaceutical Benefits Scheme, such as: mandatory price disclosure, value-based pricing, and reference pricing;

There are a number of pricing methodologies that should be evaluated for establishing and re-evaluating appropriate benefit levels for the prostheses included on the Department of Health's Prostheses List. We note that different benefit setting models may be appropriate, depending on whether:

- There is a predicate device already included on the Prostheses List
- The application is for a new listing or an amendment to an existing item on the List
- A review of existing benefit levels for groups are being re-evaluated.

The methodologies mentioned below are provided in alphabetical order, rather than in an order of preference. Such methods are being utilised by Governments setting prices for devices used in National Health Insurance systems, and may also be used by the Health Economic Working Group (HEWG) in the Australian Prostheses Listing process. We emphasise the appropriate levels of adaptation required to make these inputs applicable to the prostheses benefit setting process in the Australian Private Health Insurance market.

5.7.1 New innovative technology – no predicate

5.7.1.1 Domestic reference pricing

This may be relevant if the Prostheses is already being used in the Australian Market, following TGA approval, and/or if the Australian healthcare system has been used for the clinical and health economic evaluation of the intervention.

- Median of awarded tender prices adopted by public hospitals, or median price sold to public hospital items not procured through public tenders.
- The cost of prostheses defined in relevant clinical evidence such as that used to establish cost effectiveness.
- Adjust by some factor/ algorithm, which should account for:
    - Innovation that improves patient outcomes, clinical practice and the long term cost of care.
    - Differences in procurement practices, funding systems, product management and support.
    - The level of training and professional support required for safe and effective use. This may be higher in the first year or two of listing a new technology.
    - Provision of patient management and support required by the Sponsor over the life of the device and/or the life of the patient.

5.7.1.2 International reference pricing

International reference pricing (IRP) may be used as an input into the benefit setting process for new technologies that have not yet been launched in Australia. This may include the country of origin price. However, due to the complexity of adjusting for differences in health care systems across multiple jurisdictions, there may be significant challenges in defining algorithms to adjust median IRPs to inform benefit levels of prostheses in the Australian Private Health Insurance environment. Refer to EFPIA, 2014[1] for explanation.

5.7.1.3 Value/ Outcomes based pricing

Benefit premiums will be applied if the device improves patient outcomes or hospital quality measures and/or reduces cost of the treatment pathway, compared with alternatives.

Value based pricing has the potential to offer due rewards for innovation that affect the clinical effectiveness and cost effectiveness of new technology. This value needs to be considered across the entire treatment pathway, which for products such as Cochlear's implantable hearing systems will extend beyond the acute hospital episode and possibly for the life of the device and/or patient.

5.7.1.3 Cost Calculation Methodologies

A benefit may be established based on the cost of production, together with allowances for the R&D content, for marketing and management of the product. Evaluation of such data may be evaluated by relevant accounting, financial and medical experts.

5.7.2 Me too technology – a predicate device exists

As per the current *Guide to listing and setting benefits for prostheses***,** December 2015. - If the prosthesis under application can be compared with a prosthesis that is already listed on the Prostheses List, the group benefit for the listed prosthesis will be the basis for validating the proposed benefit for the new prosthesis.

5.7.3 Amendments to existing benefits

The opportunity to amend benefits defined for items on the Prostheses List should continue. Value based pricing and or modified cost-plus pricing methodologies are likely to be the most relevant.

Cochlear has utilised these methodologies to amend benefits on the Prostheses List where additional evidence was established to support a claim of superiority. To ensure transparency and consistency of assessment of benefits, there must be clear guidance as to the acceptable scope of Production, Distribution and Marketing costs. Copies of previous applications for amendments to benefits are available on request.

We do note that cost plus pricing methodologies may have limited application. These are extremely time consuming exercises and require access to significant amounts of commercial-in-confidence data which Sponsors of multinational companies may not be able to access. It can also be difficult to apply allocations of R&D, Marketing and other costs to an individual item on the Prostheses List.

5.7.4 Price re-evaluations

A benefit re-evaluation process should be introduced to maintain appropriate benefits for items included on the Prostheses List. It is recommended that benefits are reviewed every 2-3 years. New innovative technologies should be exempt from the first round of price re-evaluation.

Price re-evaluations may be informed by data from a number of sources, such as:

- Domestic reference pricing from the private hospital sector net of discounts and rebates. These data should for the prior 12 month period and be from credible sources. Sponsors should have the opportunity to verify that data.
- International references prices may provide some point for benchmarking, but need to be utilised with care and caution, as outlined above, to avoid unintended consequences.
- Submissions from Sponsors with data regarding:
    - Material changes in cost of production
    - Depreciation of Research & Development (R&D)
    - Consumer Price Index (CPI)
    - Volumes – economies of scale
    - Any new evidence that differentiates claims of superiority from comparators in the current group that have not already been submitted as an amendment.

The communication of any resulting reduction of Prostheses benefits must allow sufficient time for Sponsors to review, appeal and respond to the assessment. Any significant reductions in benefits will need to be phased in over a 1-2 year time frame.

5.8. h) Price data and analytics to reveal the extent of, and where costs are being generated within, the supply chain, with a particular focus on the device categories of cardiac, Intra Ocular Lens Systems, hips, knees, spine and trauma;

No comment will be made on this ToR. Cochlear's product portfolio does not span theses device categories.

5.9. i) Any interactions between Government decision-making and device manufacturers or stakeholders and their lobbyists;

No comment will be made on this ToR. - Refer to AusBiotech submission.

5.10. j) Any implications for prostheses recipients of the National Disability Insurance Scheme transition period;

Australians with a permanent severe to profound sensorineural hearing loss may be eligible for the National Disability Insurance Scheme (NDIS). Some of these individuals will be using cochlear implants or other implantable hearing devices included on the Department of Health's Prostheses List. Some of these individuals may be able to access replacement sound processors for cochlear implant and implantable bone conduction hearing systems through NDIS following an Assistive technology assessment.

5.10.1 Transition of Australian Hearing Clients to NDIS

It is proposed that services for the following groups will transition from the Hearing Services program administered by Australian Hearing to NDIS.

- Paediatric Participants
- Adults with complex needs including poor speech discrimination, profound loss, auditory neuropathy.

Currently this transition lacks a stated direction and transparency to industry and providers. As a result a significant risk is presenting where services and finances are not following the individuals in need.

Cochlear seeks opportunities to provide:

- Guidance on the eligibility criteria and the required hearing technology and services for these NDIS participants to ensure that NDIS funding models and forecasts make appropriate provisions for recipients of Implantable Hearing Solutions.
- Training to equip NDIS planners with the knowledge to recommend appropriate technology and services to participants with hearing impairment.
- Information about the procurement and logistics of providing hearing technology to participants in a timely fashion. For example, Australian Hearing currently has a 1800 # for timely access to funded replacement parts.
- This is essential to ensure that these individuals hear their best and actively participate in society.

5.10.2 NDIS participants aged > 26 years and < 65 years

The NDIS provides the opportunity for Australians with a permanent severe to profound sensorineural hearing loss using an implantable hearing device to receive funding to access the services and product required to maintain and maximise the use of their hearing devices.

At this time, the ability of these individuals to obtain benefit from NDIS funding pathways is variable and confusing. LAC (local area coordinators) and planners have different understanding / interpretation of the eligibility criteria and required products and services. As such, access to appropriate plans and funding is inconsistent and frequently incomplete. This is further complicated by a lack of available implantable hearing device service providers outside of the major metropolitan areas.

1. **Different NDIS planners are ask for different documentation for "approval" e.g. one case took months to move from obsoleted ESPrit 3G device (no standardisation of approval)**
2. **The process of getting payment is not efficient and is confusing for providers and participants.**

As such people in this age brackets must still have timely access to replacement sound processor technology through their private health insurance policies.

5.10.3 Australians aged > 65 with permanent severe to profound SNHL

NDIS does not provide for people acquiring a permanent severe to profound hearing loss over the age of 65, nor does it provide for existing Australian Hearing clients in this age group. This leaves a significant and growing demographic of hearing impaired people with no access to support for their hearing needs.

Those individuals with private health insurance should be able to access replacement sound processors through their insurance policies. However, this leaves Australia's most financially vulnerable and most severely hearing impaired exposed. A true market failure which requires government support.

5.10.4 Australians with unilateral permanent severe to profound SNHL

Not all indications for Cochlear's implantable hearing technologies may be eligible for NDIS. One specific indication, approved by the TGA, is for people who are suffering a severe to profound sensorineural hearing loss – commonly called single-sided deafness (SSD). It is not clear whether only people with a bilateral permanent severe to profound hearing loss will be eligible for NDIS. Such inequities should be avoided, however where there are limitations on timely access to medically necessary replacement technology, individuals holding relevant policies should be able to utilise their private health insurance coverage.

Until NDIS fully rolled out, we will not know what coverage will be available for Australians with a permanent severe to profound hearing impaired. PHI coverage of replacement sound processor technology must continue to support timely access for those insured.

5.11. k) Other related matters.

No other matters to discuss.

6. Conclusion

Cochlear acknowledges that there is opportunity to enhance the application and benefit setting processes of the Prostheses List. Enhancements should ensure that consumers have timely access to innovative technologies suitable for their individual needs, and that these innovations are aligned to the Government's reforms of the health care system and associated non-acute hospital service delivery models as well as the objectives of the National Science and Innovation Agenda.

6.1. Recommendation

- Update the Private Health insurance Legislative framework to support access to current, cost effective, clinical practice. This may be mean broadening the definitions of 'prostheses' and that of 'hospital' treatment Maintain the current PLAC/HESC assessment process to define benefits for innovative technology for which there is no predicate device. Additional expertise should be engaged for evaluations that extend beyond the knowledge and experience of the PLAC, CAGs, PoCE and HESC.

- Provide clarity around the costs and consequences that will be accepted for these evaluations to ensure innovations aligned to the Government's reforms of the health care system and associated non-acute hospital service delivery models are appropriately valued.

- Ensure that only credible sources of data are used and adapted to inform benefit setting processes in the Australian Private Healthcare sector.

- Establish a transparent benefit re-evaluation process that ensures benefits remain current, do not disrupt market access and maintain the value proposition of Private Health Insurance.

7. References

1. Private Health Insurance Act, 2007, Compilation Number 9.
2. *Private Health Insurance (Prostheses) Rules,* 2016 (No. 4)
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5. Reconstituted Prostheses List Advisory Committee (PLAC) Terms of Reference, October 2016.
6. Industry Working Group on Private Health Insurance Reform Final Report, February 29, 2016.
7. Panel of Clinical Experts (PoCE) Terms of Reference, September 2013
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