Improving access to breakthrough medical technology and affordability of medical devices for privately insured Australians:

Agreement between the Government and the Medical Technology Association of Australia (MTAA)

Purpose:

A commitment by the Government and the MTAA, as advocates for Australia's innovative medical technology sector, to:

- promote the sustainability of privately insured health care through rebalancing the costs of medical devices to privately insured patients, to help keep private health insurance affordable for all Australians;
- support a viable, innovative and diverse medical technology sector in Australia and local jobs; and
- improve the value of private health insurance for consumers by reducing benefits for prostheses on the Prostheses List.

The Government recognises the role of the Prostheses List in supporting the value proposition of private healthcare to Australian consumers, and how the medical technology sector contributes to this.

Duration of Agreement:

The commitments outlined in this Agreement between the Government and the MTAA are valid for the duration of the Agreement. This Agreement will operate from 15 October 2017 to 31 January 2022.

Any changes to the terms of this Agreement need to be agreed by both parties.

Principles:

The Agreement is underpinned by the following principles:

- **Stewardship** of the Australian health system and a responsibility for its ongoing sustainability.
- **Patient access** to affordable healthcare through private health insurance is an essential element of Australia's world-class healthcare system
- **Improved value** of private health insurance for consumers through benefits that enable access to safe, effective and cost-effective medical devices supplied within a competitive market.
- **Support for innovation** of healthcare through incentives to develop and deliver new clinically effective and cost effective medical devices that improve health outcomes
- **Transparency** of decision-making for all stakeholders that is informed by sharing of high quality data.
- **Integrity** of Australia's world class health system, including patient safety and high value clinical care.

Statements of Intent:

The Government intends to:

1. *Support sector stability and sustainability by:*

    - Providing certainty to the medical device industry through a stable pricing environment by implementing the benefit reductions of $303 million set out in Attachment A to this Agreement;
    - Exempting new groups added to a category from the August 2017 Prostheses List from the benefit reductions set out in Attachment A during the term of this Agreement.
    - Reflecting benefit changes in legislative instruments as appropriate and publishing this Agreement with a statement committing to this Agreement; and
    - Making no other changes to benefits on the Prostheses List during the term of this Agreement without agreement with the MTAA on behalf of the industry.

2. *Reduce the time to market for medical devices, by:*

    - Removing the current requirement for clinical evidence with 2 years of follow up data for some devices, where this is appropriate by 1 August 2018.
    - From 1 February 2018, applications for listing on the Prostheses List which have been approved by the Therapeutic Goods Authority for safety and efficacy will not have duplicative safety and efficacy assessment by PLAC and its subcommittees. The PLAC will maintain its role in assessing comparative effectiveness, cost effectiveness, product grouping and Prostheses List benefit where necessary.
    - The Minister asking the Secretary of the Department of Health to advise the Minister within 6 months on options for improved expedited pathways for listing appropriate applications with approval for safety and efficacy by the TGA.
    - Increasing the frequency of listing and giving effect to the Prostheses List to 1 March, 1 July and 1 November each year, to ensure privately insured patients have faster access to new technologies and that the medical devices industry has faster access to reimbursement, by 1 March 2019;
    - Developing and publishing key performance indicators for the PLAC and its advisory committees from 1 February 2019.

3. *Ensure Australian patients have access to safe, effective, and cost effective innovative medical devices in the private sector by:*

    - Establishing an industry working group by 31 March 2018 to develop a revised framework for benefit setting and benefit review, reflecting use of health technology assessment including evaluation of value, cost-effectiveness and innovation; use of post-market review and the operation of competitive markets in the Australian context; and
    - Establishing an industry working group by 31 March 2018 to determine how technical support services for active implantable cardiac devices should be funded. This recognises that the reductions to the benefits for medical devices in the Cardiac Category of the Prostheses List, as set out in Attachment A, may change the way

medical device companies continue to provide technical support for active implantable cardiac devices; and

- Continuing with targeted reviews of prostheses but not implementing any changes to benefit levels without agreement of the MTAA during the life of the Agreement.
- Reviewing, through the PLAC, ways of listing new targeted medical devices on the Prostheses List that do not meet the current criteria for listing, but are safe, clinically effective and cost effective to support private health insurance reimbursement for a wider range of medical devices taking into account overall costs associated with the listing. These include, but are not limited to, cardiac ablation catheters for atrial fibrillation.

4. *Improve the transparency and efficiency of the Prostheses List arrangements by:*

    - Establishing an industry Working Group by 31 March 2018, to improve the quality of information provided to applicants in the *Prostheses List – Guide to Listing and* Benefits (*the Guide*) and the Prostheses List Management System (PLMS) to support successful applications to list devices on the Prostheses List;
    - Conducting a process review of the PLAC assessment process with a view to ensuring consistent processes are adopted across the PLAC and its advisory committees and improving the quality and timeliness of written information provided to applicants at key steps of the evaluation process to enable them to better address issues with their applications; and
    - Revising cost recovery arrangements to take account of amended processes and timelines, and any associated efficiency gains, to ensure that Prostheses Listing and list management activities comply with the government's policy for recovery of the costs of all regulatory activities from the entity seeking the activity. The government will aim to implement any changes to cost recovery arrangements by 1 July 2019.

5. *Recognise superior clinical performance by:*

    - Continuing to recognise superior clinical performance (SCP) through application of the SCP suffix and a reduced benefit premium as outlined in Attachment A; and
    - Introducing a new model for SCP benefit by 1 February 2022 (or earlier by mutual agreement) through commencing work on the inclusion of measures to recognise the value of innovative technologies that deliver improved health outcomes in development of the framework for longer term benefit setting and benefit review.

6. *Support Australian medical technology innovation by:*

    - Establishing a $30 million med-tech and biotech grants program by 31 March 2018 that will be available for small to medium size enterprises (SMEs) and researchers who partner with SMEs for conducting activities that support development of new and innovative device technologies, clinical trials and associated registries, support researcher exchanges and workforce development. The allocation of grants will be overseen by a committee that includes representatives of MTP Connect, AusBiotech, MTAA and the Department of Health

The medical devices industry intends to:

1. *Support the affordability of private health insurance by:*

    - Rebalancing the costs of medical device to privately insured patients to help keep private health insurance affordable for all Australians.

2. *Participate in and support the collaborative work with the Government and the Prostheses List Advisory Committee to develop a world class, evidence-based and value-based reimbursement process for medical devices. This will include work to:*

    - improve Prostheses List processes, including through better information for applicants, pre-submission meetings for applicants and, ensuring consumers can effectively contribute to processes;
    - developing appropriate pathways for application and assessment of products;
    - developing post market review arrangements for products;
    - developing a revised benefit setting and review framework which takes into account value and innovation; and
    - continuing to participate in reform work already underway, including the review of criteria for listing devices on the Prostheses List, and the targeted reviews of existing listed products.

3. *The industry acknowledges that changes to improve Prostheses List processes to provide better services and support to industry will need to be reflected in appropriate changes to cost recovery arrangements and that the government will aim to implement any changes to cost recovery arrangements by 1 July 2019.*

Governance Arrangements:

Sound governance arrangements will underpin the Agreement to enable it to be effectively and efficiently administered.

- Representatives of the parties agree to meet at least six monthly to review the operation and progress of the Agreement and agree on data collection to assist the parties evaluate the impact of the Agreement during the term of the Agreement.
- Representatives of the parties will also evaluate the success of the Agreement in achieving its purpose in the last year of the agreement.
- No changes will be made to the Agreement without the consent of both parties.
- Appropriate safeguards will be implemented to protect the confidentiality of commercially sensitive data used to inform savings under the Agreement or any future reforms where such data would be used.

ATTACHMENT A

	1 February 2018 80% on 1 February 2018 20% on 1 August 2018	1 February 2020**
Ophthalmic	-5%	-5%
Except Groups		
Foldable	-8.5%	-8.5%
Viscoelastic	-10%	-10%
Ears Nose Throat	-5%	-5%
Except Groups (Cochlear Implants, Speech Processors, Sound Processor Accessory Kits, Implantable Bone Conduction Hearing System)	-5%	-
General Misc* **	-5%	-5%
Except Groups (Infusion Pumps, Balloon Based; Sponges; Pliable Patches, Internal Adhesives, Ligating Devices; Staples & Tackers)	-7.5%	-7%
Neurosurgical	-5%	-5%
Urogenital	-5%	-
Specialist Ortho	-5%	-
Except Groups (Screws; Surgical Accessories; Bone Cement)	-10%	-3%
Plastic and Reconstructive	-2.5%	-
Cardiac	-20%	-7.5%
Except Group (Cardiac Defect Occluders)	-10%	-10%
Cardiothoracic	-5%	-
Vascular	-5%	-5%
Except Assessment Bodies (Vascular Patches; Arterial Closure Devices; Long Term Vascular Access Devices); and Groups (Occlusion Devices – Particle; Coil, Peripheral; Polymer; Delivery Device For Occlusion Media)	-10%	-10%
Hip*	-5%	-4.5%
Knee*	-3.3%	-2.5%
Spinal	-3.75%	-3.75%

***SCP at 50% on 1 February 2018 and removed on 1 February 2019

** 1 February 2020 price change is calculated on the basis of the PL benefit on 31 January 2020

*** Group 03.01.01 is excluded from price cuts in 2018 and 2020