Office of Health Technology Assessment Technology Assessment and Access Division MDP 951 GPO Box 9848 CANBERRA ACT 2601

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PROSTHESES LIST - KEY DATES FOR NOVEMBER 2019

This circular provides information for stakeholders on the timeframe for submitting applications to list prostheses on the November 2019 Prostheses List. The dates provided in the circular are correct at the time of publishing, and any change will be advised.

From 2019, the Prostheses List (PL) will be published three times per year (effective 1 March, 1 July and 1 November), in accordance with a commitment in the Government's Agreement with the Medical Technology Association of Australia (MTAA).

PLs will continue to be published at least 10 working days before the PL takes effect to allow stakeholders to update their systems with the new information. The Department will also release an XML version of the PL to facilitate rapid update of information in stakeholder systems.

Sponsors are responsible for the accuracy of their PL data. The Department will continue to provide draft PLs for quality assurance by sponsors. An upgrade of the Department's Prostheses List Management System (PLMS) implemented in September 2018 will facilitate quality assurance of PL information by sponsors.

Once the PL has been published, any sponsor errors or errors not identified by the sponsor will be corrected in the next PL. Any errors by the Department will be notified and corrected as soon as practicable.

In preparation for this change in processing, the Department is reviewing the schedule of meetings of the Prostheses List Advisory Committee (PLAC) and the Clinical Advisory Groups (CAGs) and requirements for submitting applications for assessment by the Panel of Clinical Experts (Panel).

A schedule of meeting dates for the CAGs is at the end of this circular. Due to the introduction of a third Prostheses List per year there will only be a single meeting per CAG for the November 2019 Prostheses List.

To facilitate the progress of applications in the compressed cycle, if additional information is required to support applications following the initial assessment by two individual clinicians, sponsors will be given comprehensive feedback regarding their applications and an opportunity to address the issues raised in the assessments before the application is presented to the respective CAG.

For applications to list devices in the Panel categories, similar opportunities for feedback will be provided and sponsor responses will be referred back to the assessing clinicians for consideration.

All applicants applying to list devices or applying to change current listings should submit their applications no later than midnight on Sunday **12 May 2019**; this includes Part B - Human Tissue applications.

This deadline will also apply to applications for amendments, expansions or compressions.

This will allow the minimum time required for assessment by clinicians and consideration by the Health Economics Sub Committee (HESC) (if required) before referral to the PLAC for recommendation.

Applications for the November List can be submitted at any time before the 12 May 2019. Applications received after the 12 May 2019 will be considered for the March 2020 Prostheses List.

Applications to delete, transfer or duplicate current listings can be submitted until 6 September 2019 to allow for processing before the draft Prostheses List is produced.

Schedule of CAG meeting dates for November 2019 Prostheses List

Category	Date of Meeting
06. Specialist Orthopaedic	12 July 2019
09. Cardiothoracic	12 July 2019
05. Urogenital	12 July 2019
08. Cardiac	13 July 2019
01. Ophthalmic	15 July 2019
11. Hip	19 July 2019
13. Spinal	19 July 2019
12. Knee	20 July 2019
10. Vascular	22 July 2019