



Australian Government

Department of Health

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## **Prostheses List Supporting the Sustainability of the Medical Devices Sector**

Last updated 9 July 2020 to provide advice on the payment of fees

The Government has been considering the impact of the COVID-19 outbreak on the healthcare sector, including the medical technology industry, and in this context, the Minister for Health, the Hon Greg Hunt MP has agreed to a period of hibernation for all Prostheses List reform work covered under the Strategic Agreement with the Medical Technology Association of Australia (MTAA) of up to 12 months.

This will include pausing Industry Working Groups' activities, revision of the Prostheses List Guide, and the Revised Benefit Setting and Review Framework Industry Working Group report.

In addition, the pause will be extended to the Review of General Miscellaneous Category of the Prostheses List, and there will be no assessment of any new or amendment Prostheses List applications for products on the General Miscellaneous category, except on Part C.

This will provide predictability during these difficult times for the medical technology sector. It will allow industry and government to redirect efforts to issues relating to the impacts of COVID-19.

Questions and answers have been developed to provide all stakeholders with clarity on work related to the Prostheses List in the coming months.

### **Hibernation Period**

#### *What is the hibernation period?*

The hibernation period for the MTAA Strategic Agreement commenced on 1 April 2020 and will continue until 31 March 2021. The hibernation period may be lifted earlier if the Government and MTAA agree, for example, if the volume of elective surgeries normalises earlier than anticipated.

During the hibernation period, a number of Prostheses List activities will be paused or ceased.

The MTAA, as the peak body representing the medical device industry, has given an undertaking to the Minister for Health to strongly encourage its members to reduce the number of applications throughout the hibernation period in order to allow Government and industry to redeploy resources to critical COVID-19 response work.

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## **Prostheses List – Applications**

*Will the applications submitted in January be finalised and devices listed on the July 2020 Prostheses List?*

Applications submitted before 13 January 2020 continue to be assessed as per the usual process, and listing decisions will be made following the May 2020 Prostheses List Advisory Committee (PLAC) meeting.

The successful new and amendment applications will be effected on the Prostheses List in July 2020. This will apply to all applications, except applications for listings on the General Miscellaneous Category in Part A of the Prostheses List.

All applications lodged in January 2020 related to Part C of the PL will be assessed in accordance with the usual process.

Any applications (except Part A - Miscellaneous Category) that either have not been finalised, or were unsuccessful, will be paused until the next Prostheses List or rejected, whatever is applicable.

*What will happen with submitted applications for products from General Miscellaneous category in Part A of the Prostheses List?*

Decisions on new or amendment applications for products from the General Miscellaneous Category in Part A of the Prostheses List will be paused until the end of the hibernation period. The definition of a 'new listing' is provided below.

Only applications requesting deletions of existing Prostheses List billing codes (i.e. Delete a Listing) or requests to change the sponsor (i.e. Transfer a Listing) will be processed for devices in this category.

This exception is occurring due to pausing the General Miscellaneous category review.

*Will any applications for products in Part C of the Prostheses List be paused?*

No, there will be no pause on these applications.

*What will happen with applications for the November 2020 Prostheses List, submitted prior to, or on 10 May 2020?*

While companies have been strongly encouraged by MTAA to reduce the number of applications submitted during the hibernation period, applications made will be assessed unless they are applications for listing of products on the General Miscellaneous Category of Part A of the Prostheses List.

*Will I be able to submit an application for the March 2021 Prostheses List?*

As above, the MTAA has given an undertaking that all its members will be strongly encouraged to reduce the number of applications submitted during the hibernation period. Applications made will be processed and considered unless they are applications for listing of products on the General Miscellaneous Category of Part A of the Prostheses List.

The Government and the MTAA may agree to end the hibernation period sooner than 12 months.

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### *What is a 'new listing'?*

Any successful new, amendment, expansion, compression, or duplication application is interpreted as a ***new listing*** for the purpose of hibernation arrangements.

Amendment, Expansion, Compression, and Duplication applications apply to changes to the existing Prostheses List billing codes. This includes any application for a higher benefit for a current listing of a current product.

### **Prostheses List – health technology assessment**

#### *Do assessments going through the Medical Services Advisory Committee (MSAC) continue?*

Yes, any applications, already with the Department, undergoing MSAC assessment will continue to be assessed, consistent with the current processes.

Information on MSAC can be found on its [website](#).

### **Changes to the Prostheses List**

#### *Will the Department continue publishing three Prostheses Lists per year?*

The purpose of the hibernation is to reduce the workload for industry and government in administering the Prostheses List by reducing the number of PL updates during the hibernation period.

This will be achieved by:

- MTAA will undertake communication to members, strongly encouraging companies to reduce new PL listings during the hibernation period, in order to allow Government and industry to redeploy resources to critical COVID-19 response work.
- The July 2020 PL update will proceed with the exception of no new listings in the General Miscellaneous Category due to the pause to the review of the General Miscellaneous Category, however new listings of Part C products can continue to be assessed and, at the discretion of the Minister for Health, considered for the November update as per the standard process.
- The November 2020 PL update will proceed with the exception of no new listings to the General Miscellaneous Category, however new listings of Part C products can continue to be assessed and, at the discretion of the Minister for Health, considered for the November update as per the standard process.
- Should the hibernation continue for the full 12 months, the March 2021 PL update will proceed as for the November 2020 update, namely, no new listings to the General Miscellaneous Category, however new listings of Part C products can continue as above.

#### *Will the Department delete any prostheses from the Prostheses List during hibernation?*

No billing codes will be deleted from the Prostheses List until 31 January 2022, unless it is at the request of, or agreement with, the sponsor, there are safety concerns, or due to suspension, variation or cancellation of the Australian Register of Therapeutic Goods (ARTG) entry.

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*Will the Department reduce benefits during hibernation?*

There will be no Prostheses List benefits reductions for any products listed on the Prostheses List until 31 January 2022, unless it is agreed with the sponsor.

*Will products that are not technically suitable for listing on the Prostheses List be removed/deleted from the PL?*

No deletion of any billing codes from the Prostheses List will occur prior to 31 January 2022, unless it is agreed with the sponsor, or for safety reasons, or due to ARTG suspension, variation or cancellation.

Where a mistake is found on the Prostheses List during the hibernation period, for example, a listing is in the wrong category, the Department will communicate with the sponsor on appropriate actions. Any errors in listings will not be deemed to set a precedent for future (similar) listings.

### **Prostheses List Fees**

*Are we required to pay the Prostheses List application and listing fees, and levies for the National Joint Replacement Registry?*

Yes, you are. There are no changes to the requirements for sponsors to pay Prostheses List fees and National Joint Replacement Registry levies.

In March 2020, the MTAA asked the Government to consider waiving the Prostheses List and National Joint Replacement Registry fees and levies. The decision has now been made not to waive the fees and levies, but it was acknowledged that more flexibility could be provided in terms of the time available for sponsors for organising their payments.

The legislation requires the Prostheses List **ongoing listing fee** to be paid by sponsors twice a year, triggered by invoices in March and September. The due date for invoices generated in March 2020 has been extended until **31 July 2020**. Many sponsors have already paid their outstanding invoices and **the Department will now be sending reminders to those sponsors, who have not yet paid their fees.**

Sponsors of new products listed on the Prostheses List on 1 July 2020 are also required to pay **initial listing fees**. Invoices were sent to sponsors of successful Prostheses List applications mid-June 2020. The terms of payment for these invoices has also been extended until **31 July 2020**. If the relevant fees are not received by the Department by this extended due date, the respective products may be removed from the Prostheses List.

Many sponsors also submitted applications for 1 November 2020 Prostheses List. If the **application fee** is not paid, the product may not be listed on the Prostheses List.

The **National Joint Replacement Registry levies** occur on 30 November 2020.

**Note:** If you have any questions regarding Therapeutic Goods Administration (TGA) fees and charges, please refer to the TGA website ([www.tga.gov.au](http://www.tga.gov.au)) or contact TGA at: [info@tga.gov.au](mailto:info@tga.gov.au).

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## Reforms

### *What does the hibernation mean for the reforms?*

The hibernation period will apply to all reforms and Industry Working Group activities, including revision of the Prostheses List Guide and application forms, introduction of the abbreviated assessment pathways, and finalising the Revised Benefit Setting & Review Framework Industry Working Group Report.

The Department will preserve all work to date to ensure it can be picked up without delay. There has been much consultation to date and it is anticipated the focus of discussions when the hibernation period ends will be on finalising the policy options to be provided to the Government.

### *What does this mean for the Industry Working Groups?*

The current members' appointments to the Revised Benefit Setting & Review Framework Industry Working Group and the Quality of Information and Guidance Industry Working Group will be extended for a minimum of twelve months until 30 June 2021. However, no work will be undertaken at least until 31 March 2021.

Any feedback or comments provided to the Department have been collated and added to the existing material.

## Reviews

### *What will happen with the review of the General Miscellaneous Category of the Prostheses List?*

Ernst & Young (EY) will wrap up the draft report based on the information collated to date. There will be no further consultation or opportunity to provide feedback at this point. The review will re-commence at the end of the hibernation.

### *What will happen to other targeted reviews?*

The Department will consider the status of all reviews currently on hand recognising that the goal during the hibernation period is to minimise work for the industry and the Department to the extent possible to free up resources for COVID-19.

No deletion from the Prostheses List will occur during the life of the Strategic Agreement (which concludes 31 January 2022), unless it is agreed with the sponsor or for safety reasons.

If any individual or organisation identifies products or groups of products on the Prostheses List that in their view should be added to the list of targeted reviews, they should notify the Department. The Department will consider such notifications on a case-by-case basis. Safety concerns should continue to be raised with the TGA.

### *What decisions will still be made following PLAC recommendations?*

The Minister's delegate will continue to make decisions about listings and may make a decision to place conditions on a Prostheses List billing code. For example, the condition may specify that private health insurers are required to pay benefits for the prostheses only when it is used consistently with the hospital services identified under the specific Medicare Benefits Schedule (MBS) items.

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Such condition may clarify the intended purpose and indications for which the product was assessed and approved for listing on the Prostheses List. The condition will not change the Prostheses List benefit for the prosthesis.

**Additional Information**

*Where can I access additional information on the hibernation?*

Information on the hibernation will be made available on the [Prostheses page](#) of the Department's website.

Any further announcements will be made through a PHI Circular. More information on PHI Circulars can be found on the [Department's website](#).