



# Reduced annual charges for medical devices listed on the prostheses list

## Last updated:

1 October 2020

In response to the suspension of elective surgery due to COVID-19 and the significant impact this has had on parts of the medical devices industry, the Government has agreed to provide a 50 per cent reduction in annual charges for certain medical devices. The 50 per cent reduction in annual charges will be prescribed for the 2020-21 financial year for medical devices included in the Australian Register of Therapeutic Goods (ARTG) as Class IIa, IIb, III and AIMD and which are listed prostheses as defined in the Private Health Insurance (Prostheses) Rules (No.1) 2020 (<https://www.1.health.gov.au/internet/main/publishing.nsf/Content/health-privatehealth-prostheseslist.htm>), as in force on 8 April 2020.

## Annual charges for medical devices listed on Prostheses List for 2020-21

Class of medical device	Charge	Regulation
AIMD	\$600	Item 7(4A)(b)
Class III	\$600	Item 7(4A)(b)
Class IIa	\$470	Item 7(4A)(a)
Class IIb	\$470	Item 7(4A)(a)

These charges are in the Therapeutic Goods (Charges) Regulations 2018 (<https://www.legislation.gov.au/Series/F2018L00774>).

No action is required by eligible sponsors as the Therapeutic Goods Administration (TGA) will use the published Prostheses List (PL) as in force on 8 April 2020 with reference to the ARTG inclusion number to identify those devices which will be subject to the reduced charges.

The reduced annual charge would also apply to an ARTG entry where multiple products are included in the entry and only some products covered by the entry are listed on the PL.

Sponsors will receive an invoice in August for the 2020-21 annual charges, which will automatically include the reduced charges for such devices.

The complete [TGA fees and charges schedule](https://www.tga.gov.au/node/287173) (<https://www.tga.gov.au/node/287173>), is available on the TGA website.

Any questions relating to this can be directed to [accountsrec@health.gov.au](mailto:accountsrec@health.gov.au) (for billing and payment) or [Email us \(https://www.tga.gov.au/get-in-touch\)](https://www.tga.gov.au/get-in-touch) (for verification of medical device on the PL).

## FAQs

[Open all \(#\)](#) | [Close all \(#\)](#)

### **How can a sponsor check if their products are eligible for the reduced annual charges?**

Any medical devices which are included in the ARTG as Class IIa, IIb, III and AIMD and are listed prostheses as defined in the [Private Health Insurance \(Prostheses\) Rules \(No.1\) 2020](https://www1.health.gov.au/internet/main/publishing.nsf/Content/health-privatehealth-prostheseslist.htm) (<https://www1.health.gov.au/internet/main/publishing.nsf/Content/health-privatehealth-prostheseslist.htm>), as in force on 8 April 2020 are eligible for reduced annual charges.

### **What period is the reduced annual charges applicable for?**

The reduced annual charges apply for the 2020-21 financial year only.

### **What action is required by the sponsor to avail the reduced annual charges?**

There is no action required on the part of the sponsor. The TGA will use the ARTG inclusion number in the [Private Health Insurance \(Prostheses\) Rules \(No.1\) 2020](https://www1.health.gov.au/internet/main/publishing.nsf/Content/health-privatehealth-prostheseslist.htm) (<https://www1.health.gov.au/internet/main/publishing.nsf/Content/health-privatehealth-prostheseslist.htm>) as in force on 8 April 2020 to identify those medical devices to which the reduced annual charges apply.

### **What rate of annual charge applies to an ARTG entry that contains multiple medical devices but only some devices are on the PL?**

If an ARTG entry contains multiple medical devices and not all devices within the entry are part of the [Private Health Insurance \(Prostheses\) Rules \(No.1\) 2020](https://www1.health.gov.au/internet/main/publishing.nsf/Content/health-privatehealth-prostheseslist.htm) (<https://www1.health.gov.au/internet/main/publishing.nsf/Content/health-privatehealth-prostheseslist.htm>), the TGA will apply the reduced annual charges to such an entry.

## **What action is required if the ARTG inclusion number for a medical device on the PL as on 8 April 2020 is incorrect?**

Please contact [accountsrec@health.gov.au](mailto:accountsrec@health.gov.au) with relevant information.

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### **Topics:**

[Fees and payments \(https://www.tga.gov.au/how-we-regulate/fees-and-payments\)](https://www.tga.gov.au/how-we-regulate/fees-and-payments).

[Medical devices \(https://www.tga.gov.au/products/medical-devices\)](https://www.tga.gov.au/products/medical-devices).

[In Vitro Diagnostic medical devices \(IVDs\) \(https://www.tga.gov.au/vitro-diagnostic-medical-devices-ivds\)](https://www.tga.gov.au/vitro-diagnostic-medical-devices-ivds).