Private Health Insurance Branch Medical Benefits Division GPO Box 9848 CANBERRA ACT 2601

PHI 49/20 6 July 2020

Reduced TGA regulatory charges for certain implantable medical devices listed on the Prostheses List

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 Australian Government has agreed to provide a 50 per cent reduction in annual TGA regulatory charges for certain medical devices. The 50 per cent reduction in annual charges will be applied for the 2020-21 financial year for those medical devices included in the ARTG as Class IIa, IIb, III and AIMD and which are also listed prostheses as defined in the *Private Health Insurance (Prostheses) Rules* (No.1) 2020, as in force on 8 April 2020.

No action is required by eligible sponsors as the 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. If the ARTG inclusion number for a device on the PL as in force on 8 April 2020 is not correct, please contact the TGA by 31 July 2020.

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.

Further information can be found here: <a href="www.tga.gov.au/reduced-annual-charges-medical-devices-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-listed-prostheses-