Australian Government

Department of Health

PHI 09/22 Private Health Insurance (Prostheses) Rules (No. 1) 2022

The Private Health Insurance (Prostheses) Rules (No. 1) 2022 will commence on 1 March 2022.

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This circular provides information for stakeholders about the March 2022 Prostheses List.

The delegate of the Minister for Health and Aged Care has made the Private Health Insurance (Prostheses) Rules (No. 1) 2022, to replace the *Private Health Insurance (Prostheses) Rules (No. 3) 2021*.

The *Private Health Insurance (Prostheses) Rules (No. 1) 2022* are registered on the Federal Register of Legislation and commence on 1 March 2022.

The Prostheses List (Part A, Part B and Part C) and reports on changes from the November 2021 Prostheses List are provided in Excel and Portable Document Format at Prostheses List.

There are some amendments taking effect in the 1 March 2022 Prostheses List (PL) that the stakeholders may need to be aware about, including removal of suffix, placing the conditions on the new and existing billing codes, removal some of the PL billing codes, etc. Details on some of these amendments are provided below.

Removal of suffix Textured from the Prostheses List

The Medical Services Advisory Committee (MSAC) previously compared the clinical and cost-effectiveness of textured breast implants with smooth implants and tissue expanders and found that there had been no sufficient clinical evidence available to substantiate better clinical performance and cost-effectiveness of textured breast implants and tissue expanders over smooth devices.

Consistently with this advice the Prostheses List Advisory Committee (PLAC) recommended that the PL benefit for textured breast implants will be reduced to the level of smooth breast implants, effectively meaning removal of suffix Textured from the category 07 - Plastic and Reconstructive. A total of 13 billing codes are affected by this change.

Reclassification of surgical mesh devices to Class III

In accordance with the Therapeutic Goods (Medical Devices) Regulations 2002, surgical mesh devices were reclassified from Class IIb to Class III, and in order for the existing surgical meshes (other than urogynaecological meshes) to be eligible for the transitional arrangements, sponsors were required to submit a Class III application to the TGA by 1 December 2021. Further information is on the TGA website.

The devices that have not been reclassified to Class III or meet the requirements for transition are no longer eligible for inclusion in the Australian Register of Therapeutic Goods (ARTG) and are expected to be cancelled by sponsors or will be cancelled by the TGA. One of the criteria for listing the device on the Prostheses List is that the device is appropriately included in the ARTG. Respectively, 40 billing codes for the surgical meshes have been deleted from the PL, and some billing codes have been amended to ensure only eligible devices remain listed on the PL.

Deletion of some billing codes from the Prostheses List

The MSAC has advised that CARGEL/BST-CarGel is not cost-effective as there is insufficient evidence to support non-inferior safety and superior effectiveness of BST-CarGel compared with microfracture (MF) alone (MSAC application 1569), and that there is insufficient evidence to demonstrate non-inferior safety, superior effectiveness and cost-effectiveness of JointRep™ in conjunction with MF compared with MF alone, and that the comparison of JointRep™ plus MF versus BST CarGel™ plus MF was uninformative and did not demonstrate non-inferior safety and effectiveness (MSAC application 1578).

PLAC noted the MSAC advice and recommended deletion of both PL billing codes.

The PLAC also noted two billing codes that were listed in grouping 06.03.07.05 - Specialist Orthopaedic-Soft Tissue Fixation Devices - Button/thread/tape or Button/thread/button, but did not have either fixation button or anchor [only fixation tapes] and agreed that these PL billing codes were listed incorrectly.

Consistently with the above, it was decided to delete these billing codes from the PL.

Conditions placed on the new and existing billing codes

PLAC noted that the ARTG entry 191454 stated for the billing code HW856 explicitly refers to the use of the device in hindfoot and ankle fusion procedures and agreed that in this particular case, placing a condition on the PL billing code clarifying that the Prostheses List benefit is limited to the reimbursement for the use of the device in these conditions is warranted.

There are also conditions placed on five new billing codes for the devices intended for use in the procedures related to dura defect repair.